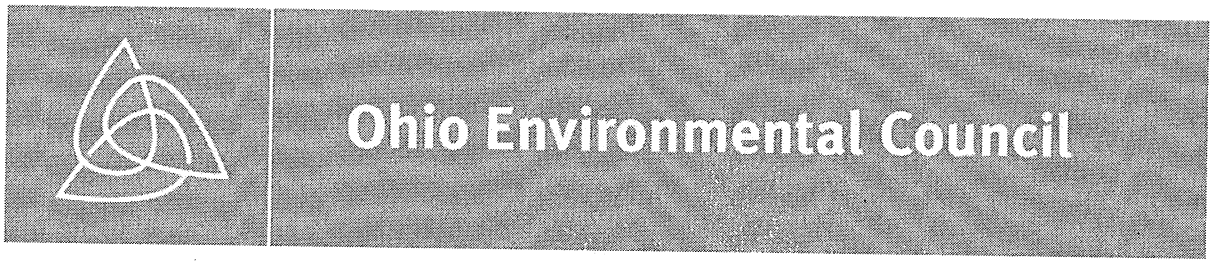
EXHIBIT

C-127



BY POSTAL MAIL

April 10, 2018

Administrator Scott Pruitt
United States Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mailcode: 1101A
Washington, DC 20460

Director Peter C. Grevatt
Office of Ground Water and Drinking Water
United States Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mailcode: 4101M
Washington, DC 20460

Acting Principal Deputy Assistant Administrator Charlotte Bertrand
Office of Chemical Safety and Pollution Prevention
United States Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mailcode: 7101M
Washington, DC 20460

Regional Administrator Cathy Stepp
Region 5
United States Environmental Protection Agency
77 West Jackson Boulevard
Chicago, IL 60604

RE: Petitions for Rulemaking regarding Perfluoroalkyl Substances (PFASs)

Dear Administrator Pruitt, Director Grevatt, Acting Principal Deputy Assistant Administrator Charlotte Bertrand, and Regional Administrator Cathy Stepp:

On behalf of the Ohio Environmental Council ("OEC"), please find enclosed for submission a Petition for Rulemaking to establish regulations for perfluorooctanoic acid ("PFOA") and perfluoroalkyl substances ("PFAS" or "PFASs") pursuant to the federal Administrative Procedure Act ("APA"), the Clean Water Act ("CWA"), Safe Drinking Water Act ("SDWA"), and the Toxic Substance Control Act ("TSCA"). The Petition makes seven separate requests under the aforementioned federal laws. The United States Environmental Protection Agency ("EPA") must consider this petition with due diligence and grant these seven requests in order to protect the environment as well as the health of hundreds of millions of present and future Americans.

The regulation of PFOA and PFASs is necessary for the protection of human health and the environment. PFOA and PFAS contamination is both a global and a localized problem. In February 2018, Ohio Attorney General Mike DeWine filed suit against DuPont for its pollution of the Ohio River with PFOA and its endangerment of Ohio's public water systems.

The OEC recognizes that the EPA has recently scheduled a "National Leadership Summit to Take Action on PFAS." In his announcement, EPA Administrator Scott Pruitt stated that the

agency would provide national leadership while "ensuring that our state, tribal, and local partners have the opportunity to help shape our path forward." The EPA and all state governors that attend this Summit should use this Petition for Rulemaking as a federal baseline from which all states develop their own protective programs. By creating a federal baseline that protects the Waters of the United States and drinking water supplies from PFOA and PFASs, the EPA would demonstrate the national leadership Administrator Pruitt seeks.

With these considerations in mind, the OEC petitions the EPA to take immediate action to propose, allow for public comment, and promulgate standards and regulations related to perfluoroalkyl substances under the aforementioned laws.

We thank you in advance for your prompt and diligent attention to this matter and look forward to your response.

Respectfully submitted,

Trent Dougherty
General Counsel
The Ohio Environmental Council
1145 Chesapeake Avenue, Suite I
Columbus, OH 43212
tdougherty@theoec.org
(614) 487-7506

Chris Tavenor
Law Fellow
The Ohio Environmental Council
1145 Chesapeake Avenue, Suite I
Columbus, OH 43212
ctavenor@theoec.org
(614) 487-7506

PETITION TO THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OHIO ENVIRONMENTAL COUNCIL,
1145 Chesapeake Avenue, Suite I
Columbus, Ohio 43212

Petitioner,

Filed with:

SCOTT PRUITT,
In his official capacity as
EPA Administrator,
United States Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mailcode: 1101A
Washington, DC 20460

PETER C. GREVATT,
in his official capacity as
Director for the Office of Ground Water and Drinking Water (OGWDW),
United States Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mailcode: 4101M
Washington, DC 20460

CHARLOTTE BERTRAND,
in her official capacity as
Acting Principal Deputy Assistant Administrator for the Office of Chemical Safety and Pollution Prevention (OCSPP),
United States Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Mailcode: 7101M
Washington, DC 20460

CATHY STEPP
in her official capacity as
Regional Administrator for Region 5,
United States Environmental Protection Agency
77 West Jackson Boulevard
Chicago, IL 60604

Petitions for Rulemaking regulating perfluorooctanoic acid and other perfluoroalkyl substances to protect public health, water quality, and the environment, under the Clean Water Act, Safe Drinking Water Act, and Toxic Substance Control Act.

Submitted April 10, 2018

Contents

Executive Summary

Any party may petition a federal agency for an agency rulemaking under the APA and other applicable laws. The OEC exercises this right through this Petition for Rulemaking by requesting regulations promulgated by the EPA that regulate PFOA and other PFASs. PFASs pose a significant risk to human health and the environment and the EPA must take immediate action.

PFOA has been linked by scientists to a variety of health risks including high cholesterol, ulcerative colitis, thyroid disease, testicular and kidney cancer, and pregnancy-induced hypertension. Insufficient research exists to definitively state the health risks of all PFASs, and that fact is the exact reason why the EPA should regulate this immense group of over 3000 substances. Not only might many of these PFASs have a range of individual side-effects, their inundation throughout U.S. waterways may lead to mixture toxicity, a question unaddressed by the EPA in its PFOA Health Advisory.

Therefore, the OEC proposes the following regulations:

Under the Clean Water Act:

(1) Water Quality Criteria for PFOA at 0.014 micrograms per liter;

(2) Water Quality Criteria for PFASs at 0.07 micrograms per liter;

(3) A National Water Quality Standard for the Ohio River that includes Water Quality Criteria at 0.014 micrograms per liter for PFOA and 0.07 micrograms per liter for PFASs.

Under the Safe Drinking Water Act:

(4) A Primary Drinking Water Regulation for PFOA at 0.014 micrograms per liter;

(5) A Primary Drinking Water Regulation for PFASs at 0.07 micrograms per liter;

Under the Toxic Substances Control Act:

(6) Rules prohibiting the manufacture, processing, and distribution in commerce of PFOA across the entire United States; and

(7) A Section 4 Testing Order to all persons who manufacture or process, or intend to manufacture or process, any PFAS.

We have provided these proposed regulations in **Attachment I.** The EPA must respond to these requests for rulemaking within a reasonable timeframe as required under the APA. In addition, the EPA must respond to the rulemaking requested under TSCA within 90 days, per TSCA requirements.

The seven rulemakings the OEC requests in this petition are necessary to protect the public from the human health and environmental risks of PFOA and PFASs. Numerous communities and regions across the country, from Parkersburg, WV and Southeast Ohio to Minneapolis, MN and New Jersey, have been rocked by PFOA and PFASs. The EPA must act to protect every American's right to safe drinking water. The rules requested are a necessary step toward securing that goal.

I. Under its right to Petition for Rulemaking, the OEC requests that the EPA regulate PFOA and other PFASs because they endanger human health and the environment.

The OEC is a nonprofit organization created in 1969 that thrives nearly 50 years later because of individuals and groups working together to protect and restore Ohio's natural resources and beauty. The OEC continues to pursue its mission to secure healthy air, land, and water for all who call Ohio home. The OEC has a vision of a clean, beautiful Ohio where diverse people, innovation, all of our natural treasures thrive.

PFOA and other PFASs have plagued the people of Ohio for decades as a serious public health risk, both as a known and unknown threat. Since the late 1990s, Southeast Ohio has suffered through a long history of civil class action lawsuits as the region's residents pursued damages from DuPont, the owner of the Washington Works chemical plant at the time (the plant is now owned by DuPont's spinoff company, Chemours). While significant progress has been made at the federal level to regulate such companies, the EPA has not taken significant action to protect the waters of the United States or public water systems from PFOA and PFASs other than through a non-binding Drinking Water Health Advisory.

State governments and customers of public water systems should not need to resort to bringing post-injury statutory and common law claims against polluting companies that damage their health and well-being. The public health threat itself should be controlled and eliminated before harm occurs. The EPA has a legal and moral obligation to promulgate regulations that protect human health and the environment, require point sources to install technology that limits the emission of dangerous and toxic pollutants into waters of the United States, and provide the means through which public water systems may protect their consumers from drinking water contaminants.

The OEC submits this Petition for Rulemaking regarding PFOA and PFASs because it sees the substantial danger that these substances pose to human health and the environment. At the same time, the US lacks rules and countermeasures that adequately protect its citizens. These rulemakings are a first step toward eliminating the substantial risks posed by FPOA and PFASs.

a. The Ohio Environmental Council has a right to petition the Administrator under 5 U.S.C. §553(e), and should receive a response within a reasonable time.

The First Amendment to the United States Constitution enshrines the right of each and every U.S. citizen to petition their federal government: "Congress shall make no law...abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and *to petition the government for a redress of grievances.*"[1] This right to petition inexorably links with the First Amendment's dedication to the free flow of ideas, because the right to petition clause assures the public that "decision-makers will be sufficiently informed to carry out their function."[2] However, the First Amendment did not include a right for the government to

[1] U.S. Constitution, Amendment I, emphasis added.

[2] *Osborn v. Pennsylvania-Delaware Serv. Station Dealers Ass'n*, 499 F.Supp. 553, 556 (D.Del.1980).

officially respond or even consider a petition's call for a redress to particular grievances.[3]

Fortunately, The APA builds on the First Amendment's "right to petition." First, the APA provides that "each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule."[4] This law embodies the policy that the public should participate in the regulatory process and that just as legislators are beholden to listen to the needs of their constituents, regulatory agencies must listen, too.

Furthermore, the agencies must not only listen, they must also respond, pushing the law beyond just the right to petition built into the U.S. Constitution. The APA states: "Prompt notice shall be given of the denial in whole or in part of a written application, petition, or other request of an interested person made in connection with any agency proceeding. Except in affirming a prior denial or when the denial is self-explanatory, the notice shall be accompanied by a brief statement of the grounds for denial."[5]

When a citizen, or group of citizens, believes they have a grievance deserving redress, they not only may petition the federal government, the government must respond. And not only must it respond, it must provide, at the very least, a brief statement of the grounds for denial if it chooses to reject the petition, unless the denial is self-explanatory.

But even when denying a petition for rulemaking, an agency cannot base its decision on arbitrary reasoning. When the EPA responds to a petition for rulemaking, "its reasons for action or inaction must conform to the authorizing statute."[6] In *Massachusetts v. EPA,* the Supreme Court considered the EPA's reasons for choosing not to regulate greenhouse gases, specifically in response to a petition for rulemaking pursued by states from across the nation. The EPA provided a list of reasons for why they chose not to regulate greenhouse gases under the Clean Air Act, but because those reasons weren't grounded in the statute, the EPA's response to the relevant petition for rulemaking was insufficient.[7] Thus, when a petition for rulemaking lands on the desk of a federal official delegated the authority to make the changes requested in the petition, they must respond. And when they respond, they must ground their reasoning for denial, or approval, in the statutory grounds under which the petition seeks redress.

With this petition, the OEC exercises its right under the APA to petition the Administrator of the EPA to exert his legal authority to commence rulemaking procedures that will protect human health, aquatic life, water quality, and the environment. The OEC respectfully requests that the EPA respond within a reasonable time, and if the agency decides to deny the petition, that it

---

[3] This oversight in the First Amendment eventually created a divide in public access to the immense administrative state that slowly formed in this country over the past two and a half centuries. See *We the People Found., Inc. v. United States*, 485 F.3d 140, 143 (D.C.Cir.2007). See also *Stengel v. City of Columbus, Ohio*, 737 F.Supp. 1457 (S.D.Ohio 1988).

[4] 5 U.S.C. §553(e).

[5] 5 U.S.C. §555(e).

[6] *Massachusetts v. E.P.A.,* 549 U.S. 497, 533, 127 S.Ct. 1438, 1462, 167 L.Ed.2d 248 (2007).

[7] Specifically, the Court stated: "While the President has broad authority in foreign affairs, that authority does not extend to the refusal to execute domestic laws." Id. at 534.

provides prompt notice of such denial with a statement of the grounds for denial as required under 5 U.S.C. §555(e) and *Massachusetts v. EPA*.

b. The United States Environmental Protection Agency has the authority to regulate perfluorooctanoic acid and perfluoroalkyl substances under the Clean Water Act, the Safe Drinking Water Act, and the Toxic Substance Control Act.

The OEC pursues this petition for rulemaking under three separate statutory grounds. Each rulemaking can stand under the weight of its own statutory authority, though to solve this problem entirely the EPA should implement all requested rulemakings. First, the OEC petitions the EPA to regulate PFOA and other PFASs under the Clean Water Act by developing Water Quality Criteria and a nationally promulgated Water Quality Standard for the Ohio River. Second, the EPA should regulate PFOA and other PFASs under the Safe Drinking Water Act by issuing a national Primary Drinking Water Regulation that covers those contaminants. Third, the EPA should regulate PFASs under the Toxic Substances Control Act. Under TSCA, it should require testing of the nearly 3,000 PFASs under Section 4 of the Act. Next, it should outright ban the manufacture and import of PFOA and all products that include PFOA under the Act's authority in Section 6. While the statutory authority under each of these laws is more fully detailed in later sections of this Petition, each authority can be summarized as follows.

Under the CWA, the Administrator has the authority and mandate to promulgate Water Quality Criteria under 33 U.S.C. §1313 that accurately reflect scientific knowledge regarding the health effects of particular contaminants. Similarly, the Administrator has the authority and mandate to promulgate Water Quality Standards when doing so is necessary to protect the environment and public health under 33 U.S.C. §1314 when states fail to promulgate adequate Water Quality Standards.

Under the SDWA, the Administrator has the authority to promulgate Primary Drinking Water Regulations under 42 U.S.C. §300g-1. These regulations protect human health when public water systems are likely to have concentrations of certain contaminants, and such regulation represents a meaningful opportunity for the EPA to protect customers of public water systems.

Under TSCA, the Administrator may regulate certain chemical substances that present or will present unreasonable risks of injury to health or the environment. Under Section 6 of TSCA, EPA maintains the authority to prohibit the manufacture, processing, or distribution in commerce of a "particular use" of a chemical substance if the use presents an unreasonable risk to the general public or susceptible subpopulations.[8] Furthermore, Under Section 4 of TSCA, the Administrator may require testing of a chemical substance that may present an unreasonable risk of injury to health or the environment, but there is insufficient information and experience upon which the effects of such can reasonably be determined or predicted.[9]

Because separate statutory grounds exist for the regulation of this substance under three separate laws within the purview of the EPA, the Administrator must consider each of these requests

[8] 15 U.S.C. § 2605(a).
[9] 15 U.S.C. § 2603(a).

separately from one another. Therefore, if the Administrator decides to promulgate a rule under one statutory ground, but not the others, the OEC respectfully requests a statement of why the Administrator has chosen not to regulate under those particular statutes. If the Administrator decides to deny the petition in its entirety, the OEC respectfully requests a statement of grounds for denial that explains separate reasons under each of the three Acts: The CWA, the SDWA, and TSCA, as required by the Supreme Court in *Massachusetts v. EPA*.

II. The EPA should regulate PFOA and PFASs because they are human health hazards and unreasonable threats to the environment.

The EPA has been painfully aware of the human health and environmental impact of PFOA and PFASs since the early part of the twenty-first century. The publicized story of PFOA begins back in 2001, when Cincinnati lawyer Robert A. Bilott wrote to the EPA regarding the threat the substance posed to human health and the environment.[10] That same year, DuPont settled with a family that had alleged that PFOA had harmed them and their cattle.[11] In 2002, EPA announced that in a separate settlement deal, DuPont had "agreed to replace the water supply of any resident whose water contains more than 14 parts per billion of [PFOA]."[12] However, even at that time, DuPont's own studies showed that levels of PFOA much lower than 14 parts per billion could harm the health of its employees and residents that lived in nearby communities.[13]

As the years passed and the facts piled up, Ohio attorneys filed class-action lawsuits against DuPont. While these lawsuits are important, they do not provide solutions to the underlying contamination and human health problems. PFOA remains unregulated by the EPA. It remains unregulated in Ohio and in West Virginia. While a few states have chosen to directly regulate PFOA and in some cases PFOS, greater action is needed to protect Ohioans and Americans. In addition, thousands of PFASs similar to PFOA are currently manufactured, produced, and used throughout the United States. What's worse, little to no data exists on whether PFASs cause an unreasonable risk to human health and the environment.

For the record, the OEC recognizes that EPA has taken some steps toward fully regulating PFOA and other PFASs. In 2006, the EPA asked eight companies to reduce PFOA emissions to all media by 95 percent by 2010, and all eight companies committed to this goal.[14] This program has seen some success. Some companies stopped manufacturing and importing these substances,

---

[10] Ken Ward Jr., *Dupont agrees to pay $107 million*, THE CHARLESTON GAZETTE, (September 10, 2004), available at: http://newslibrary.cnpapers.com/cgi-bin/texis/search/+5meZc9jeShbtqyiwGmaAnDam1pdDBaq8a5nBBcnMnDBqzmxwwwmzme1-wwwhFq0eRGlnGeRRHmqwceRkHmGprveRDxxLo5eRS3t+XXXtFqwrFqw/storypage.html?id=47d94c7062.

[11] Id.

[12] 14 parts per billion is equivalent to 14 micrograms per liter, over a hundred times more than the 0.07 micrograms per liter eventually established by the U.S. EPA in its Health Advisory. Id.

[13] Id.

[14] Arkema, Asahi, BASF Corporation, Clariant, Daikin, 3M/Dyneon, DuPont, and Solvay Solexis participated in the PFOA Stewardship Program. *Fact Sheet: 2010/2015 PFOA Stewardship Program*, UNTED STATES ENVIRONMENTAL PROTECTION AGENCY, (December 10, 2017), https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/fact-sheet-20102015-pfoa-stewardship-program#launch.

especially PFOA; other companies left the industry.[15] However, many companies just switched to other PFASs. When each company selects a new PFAS to use as a replacement for an old substance, yet another unregulated substance enters the market and subsequently the waters of the United States.

The OEC also credits the EPA for developing a robust reporting tool under the Toxic Substances Control Act for the family of PFASs. EPA reviews substitutes for PFOA under its New Chemicals Program. It has performed these reviews since 2000, but these reviews do not place any binding regulations on the manufacture or import of such substances other than reporting requirements.

In 2016, the EPA issued a Health Advisory for PFOA under the Safe Drinking Water Act after monitoring it as an unregulated contaminant, yet chose not to promulgate a Primary Drinking Water Regulation for PFOA or any PFAS. The EPA has hinted that it might still consider such an option, but as of now it has not made any direct action toward promulgating such a regulation.

These steps, while headed in the right direction, are simply insufficient to protect the public. Even with these voluntary actions and health advisories, PFOA and other PFASs still exist in U.S. and Ohio waterways and public water systems. Companies around the world continue to use and produce PFOA.[16] If the EPA is to correctly do its job and protect human health and the environment, it must promulgate rules that ensure substances like PFOA do not, and will never again, pose unreasonable risks to Americans.

The following subheadings will discuss the dangers of PFOA in the context of the broader family of PFASs and their persistence throughout the environment. If the EPA promulgates rules governing PFOA, it should also consider a broader regulation that covers all PFASs. They will outline the health risks of PFOA as determined by the best available science, and provide a review of the reasonably available literature regarding the health risks of other commonly used PFASs. They will discuss why the present Health Advisory covering PFOA is insufficient to protect human health and the environment. They will explain what certain governmental entities have proposed as reasonable regulations that would protect the public from the dangers of PFOA and PFASs. Finally, this section will outline the technology already available for public water systems to treat their water supplies for PFASs, while also emphasizing the fact that these public water systems should not bear the sole burden of protecting their residents.

The OEC hopes that the EPA will engage closely with this complicated issue and go beyond its current work on PFASs. The EPA has the opportunity to show the American public that it can and will protect it from the thousands of unregulated PFASs that permeate the environment. Given the wealth of knowledge (and lack thereof in certain instances) that has been established on PFOA and other PFASs over the past twenty-some years, EPA has the data necessary to change this nation's regulations. If the Agency does not have the willpower to protect the public,

---

[15] Id.

[16] See *DuPont finds high levels of C8 in Chinese Workers*, BEASLEY ALLEN LAW FIRM, (November 6, 2008), http://www.beasleyallen.com/news/dupont-finds-high-levels-of-c8-in-chinese-workers/. See also Sharon Lerner, *Under DuPont Bridge: The Teflon Toxin Goes to China*, THE INTERCEPT, (September 15, 2016), https://theintercept.com/2016/09/15/the-teflon-toxin-goes-to-china/.

the public will know exactly whom to blame when these PFASs continue to accumulate across the country, posing untold risks to human health and the environment.

a. The thousands of perfluoroalkyl substances on the market endanger human health and the environment.

PFASs have enhanced molecular properties due to the "strong electronegativity and small atomic size of fluorine."[17] Because of these beneficial properties, many companies use them in a wide variety of products and for a wide array of uses.[18] The most well known PFAS, PFOA, was used as a "processing aid . . . during the polymerization of tetrafluoroethylene to make polytetrafluoroethylene (e.g., Teflon™)."[19]

PFOA in particular was used "as an aqueous dispersion agent" due to its useful chemical properties. One of its most useful properties is its stable nature; it is solid at room temperature, has a low vapor pressure, and has a melting point of 50 to 60 degrees Celsius.[20] In particular, it is important to note that PFOA is stable in water at 25 degrees Celsius, and stable "when bound" in the air.[21] The EPA importantly notes the following environmental characteristics of PFOA:

> PFOA is stable in environmental media because it is resistant to environmental degradation processes, such as biodegradation, photolysis, and hydrolysis. In water, no natural degradation has been demonstrated, and dissipation is by advection, dispersion, and sorption to particulate matter. PFOA has low volatility in ionized form, but can adsorb to particles and be deposited on the ground and into water bodies. Because of its persistence, it can be transported long distances in air or water, as evidenced by detections of PFOA in the arctic media and biota, including in polar bears, ocean-going birds, and fish found in remote areas....PFOA is present in ambient air and seawater globally."[22]

However, while PFOA is the best known PFAS, numerous other long-chain PFASs have been identified by the scientific and regulatory community as having potential health risks.[23] But even while the EPA has released an immense body of knowledge on their understanding of PFOA, PFOS, and other long-chain PFASs, long-chain PFASs are just a small subset of thousands of PFASs. PFOA and PFOS are not the only long-chain PFASs considered for regulation throughout the world, either. Within PFOA's direct family of perfluoroalkyl carboxylic acids (PFCAs), perfluorononanoic acid ("PFNA"), perfluorodecanoic acid ("PFDA"),

---

[17] Zhanyun Wang, Jame C. DeWitt, Christopher P. Higgins, and Ian T. Cousins, *A Never Ending Story of Per- and Polyfluoroalkyl Substances (PFASs)*, 51 Environ. Sci. Technol. 2017, 2508 - 2518, 2508, https://pubs.acs.org/doi/pdf/10.1021/acs.est.6b04806.

[18] Id.

[19] *Drinking Water Health Advisory for Perfluorooctanoic Acid (PFOA)*, UNTED STATES ENVIRONMENTAL PROTECTION AGENCY, at 15, (May 2016), https://www.epa.gov/sites/production/files/2016-05/documents/pfoa_health_advisory_final_508.pdf.

[20] Id.

[21] Id. at 16.

[22] Id.

[23] "Since the late 1990s, multiple long-chain PFASs (perfluoroalkyl carboxylic acids (PFCAs) with ≥7 perfluorinated carbons, perfluoroalkanesulfonic acids (PFSAs) with ≥6 perfluorinated carbons, and their precursors), in particular perfluorooctanoic acid (PFOA) and perfluorooctanesulfonate (PFOS), have attracted world-wide attention in the scientific and regulatory community and among the public." Supra FN 17, at 2508.

perfluoroundecanoic acid ("PFUnA"), perfluorododecanoic acid ("PFDoA"), perfluorotridecanoic acid ("PFTrA"), and perfluorotetradecanoic acid ("PFTeA") have all been considered for regulation by certain governmental entities. Each of those compounds is a longer carbon chain than PFOA - for instance, PFTeA has 14 carbon chains, as opposed to PFOA's 8 carbon chains.[24]

Companies still produce these other PFASs, both short and long-chain, in high volumes, and some of them have been slated to replace the well-known long-chain PFASs like PFOA or PFOS. Current literature reviews note that "little to no information [exists in the public domain] about their fate/transport, exposure, and toxicological effects...or even awareness to study them...although existing evidence suggests a need for concern."[25]

Between 2012 and 2017, approximately 4,066 peer-reviewed articles were published regarding PFOA.[26] These articles provide the EPA and other decision-makers with the necessary information to understand the dangers that the substance poses to human health and the environment. With the exception of a few other PFASs, like PFOS, PFNA, PFDA, many PFASs have little scientific literature exploring their chemical properties, health effects, and environmental risks. Consider "GenX." GenX has been touted as a potential replacement for PFOA.[27] However, as of 2017, only 26 peer-reviewed articles have analyzed the substance.[28]

The OEC believes that the EPA should not allow any of these PFASs into our waterways until scientific literature properly establishes the safety of each substance individually and in the aggregate. Over the past decade and a half, the EPA has constantly revised its guidelines and suggestions regarding PFOA, and even now when scientists have identified a laundry list of probable health risks linked with PFOA, the EPA has still refused to promulgate regulations covering even just PFOA. The American public cannot afford to wait for the United States government to go through the same process with each PFAS.

Consider the following issues that PFASs present for human health and the environment, as identified in *Environmental Science & Technology*:

(1) All PFASs "ultimately transform into highly stable end products, which are usually the highly persistent perfluoroalkyl or perfluoroalkyl(poly)ether acids."[29]

(2) Due to their ability to travel vast distances while remaining stable, PFASs produced in certain countries will lead to distribution of PFASs and their end products across the world, "in the environment, wildlife, and humans."[30]

---

[24] Id. at 2510.

[25] Id.

[26] Id.

[27] GenX has experienced its own host of problems in the eyes of the public already. It has been detected in public and private water supplies in the Cape Fear River basin in North Carolina, and Chemours was ordered to provide bottled water to residents in the area. The company has received subpoenas regarding their discharges of GenX in North Carolina. See Catherine Clabby, *GenX Questions Continue: What about Food?*, COASTAL REVIEW ONLINE, (February 5, 2018), https://www.coastalreview.org/2018/02/genx-questions-continue-food/.

[28] Supra FN 17, at 2510.

[29] Id. at 2511.

(3) Very little research has been performed on the toxicity of most PFASs, with most studies performed by industry itself.[31]

(4) Many countries have failed to consider "mixture toxicity." Regulatory paradigms should consider the dangers of exposure to large numbers of known and unknown PFASs simultaneously, not just concentrations of individual substances like PFOA one at a time.[32]

(5) Replacing one PFAS with another PFAS (such as PFOA with GenX) "does not solve issues in relation to PFASs as a whole group - it will only increase the numbers of PFASs on the market and the difficulties in tracking them."[33]

This is a non-exhaustive list of the issues connected with PFASs. The EPA has spent resources focused on PFOA and has required the registration of new uses for PFASs as they come to market through its Significant New Uses rule, but these actions do not scratch the surface of the immense iceberg of complications that could occur as companies continue to expand the use of thousands of different PFASs. It takes time for the EPA to identify which PFASs might pose a risk - only recently in January 2018 did the EPA request sampling of GenX (a PFOA replacement) in water supplies near the Washington Works facility of Chemours, a subsidiary of DuPont.[34]

The precautionary principle represents a cornerstone of conservation and environmental protection. Even in the absence of fully established causal relationships, regulatory agencies should take precautionary measures that protect human health and the environment from potential presently unquantifiable risks. When considering the risks of PFASs, the EPA should follow the precautionary principle and restrict the manufacture and use of these substances and develop adequate regulations that protect our nation's waters until science establishes which ones are safe. Not only could each PFAS pose an individual health risk, but when combined together all PFASs pose a potential problem due to potential mixture toxicity.

As for PFOA, the EPA need not follow the precautionary principle, as the following subsections show. The science has established the dangers of PFOA and implicates the dangers of PFASs. States and international bodies have chosen to regulate PFOA and technology exists to clean our public water systems of PFOA. The following subsection demonstrates why the EPA must regulate PFOA to protect human health and the environment.

---

[30] Id.

[31] Id. at 2512.

[32] Id.

[33] Id. at 2513.

[34] See *EPA Region III Letter. Request for sampling; GenX in water supplies, ooctanoic Acid (PFOA)*, UNTED STATES ENVIRONMENTAL PROTECTION AGENCY, (January 11, 2018), https://www.epa.gov/pfas/epa-region-iii-letter-request-sampling-genx-water-supplies.

b. PFOA poses serious risks to human health and the environment.

The risks PFOA poses to human health and the environment fit into three silos. First, PFOA poses a direct risk to human health through exposure within the bloodstream. The C8 Science Panel has made a number of conclusions regarding the relationship between PFOA exposure and certain health risks. Second, PFOA poses a risk within public water systems - PFOA has inundated a number of public water systems across the country, and if the EPA is to properly protect Americans from the aforementioned health risks, they must properly regulate PFOA concentrations within public water systems. Finally, because PFOA is a highly stable compound, it has found its way into the environment across the country and the world. The EPA must promulgate regulations that properly account for this accumulation, and implement rules that provide the tools necessary rehabilitate regions with high exposure to PFOA.

i. PFOA poses a direct risk to human health because it has a probable link to numerous human diseases, including certain cancers, heart disease, autoimmune disease, thyroid disease, and pregnancy-induced hypertension.

The Ohio Department of Health has issued a simple fact sheet that is intended to educate the public on the health risks of PFOA, which it identifies as "C8," DuPont's internal name for the substance.[35] Following the scandal associated with DuPont's Washington Works facility in West Virginia that released high levels of PFOA into the Ohio River and surrounding public water districts, scientists began to engage in a robust analysis on the substance's effects on human health. According to the Ohio Department of Health, the Centers for Disease Control measured the blood of thousands of individuals for 12 PFASs, including PFOA.[36] PFOA was discovered in almost every single person tested, though the PFOA levels have dropped significantly between 2000 and 2010.[37]

As a result of the class action lawsuit connected with the DuPont Washington Works facility, a West Virginia Court ordered an immense health study involving 70,000 participants from the region.[38] Blood data and health histories of these participants were used by the C8 Science Panel, which after years of study made comprehensive conclusions regarding the health risks of PFOA.

High Cholesterol

The C8 Science Panel concluded that there is a *probable link* between PFOA and high cholesterol, or hypercholesterolemia.[39] High levels of cholesterol can cause it to build up on the

---

[35] See *C8 Community Fact Sheet*, OHIO DEPARTMENT OF HEALTH, (Last Updated May 2, 2017), https://www.odh.ohio.gov/-/media/ODH/ASSETS/Files/eh/Chemical-Fact-sheets/041-C-8-Community-Fact-Sheet-rev02-20170502.pdf?la=en.

[36] Id. at 2.

[37] Id.

[38] Id.

[39] *Probable Link Evaluation for heart disease (including high blood pressure, high cholesterol, coronary artery disease)*, C8 SCIENCE PANEL, (October 29, 2012), http://www.c8sciencepanel.org/pdfs/Probable_Link_C8_Heart_Disease_29Oct2012.pdf, emphasis added.

walls of arteries, potentially leading to heart disease and stroke.[40] Eight studies reviewed by the panel identified a positive association of PFOA with high cholesterol, with four of the eight studies concluding that a statistically significant association existed. These first studies found that "the magnitude of effect of PFOA on cholesterol was greatest in the general population low exposure setting, and lowest in the occupational high exposure setting."[41]

In the C8 Science Panel's own studies conducted on links between cholesterol and PFOA, it connected "lipids and PFOA in a cross-sectional study of 12,000 highly exposed children and adolescents in the mid-Ohio valley."[42] Even after adjusting for age, BMI, fasting, gender, and exercise levels, the study found a "steady increase in cholesterol with increasing serum PFOA."[43] This conclusion was in a similar cross-sectional study performed on 46,000 adults "who were not taking lipid-lowering drugs."[44] Based on a consideration of all the evidence, the C8 Science Panel concluded "that there is a probable link between exposure to PFOA and diagnosed high cholesterol."[45]

Ulcerative Colitis

The C8 Science Panel concluded that a probable link exists between PFOA and ulcerative colitis.[46] Ulcerative colitis is a type of inflammatory bowel disease, the other most common bowel disease being Crohn's disease.[47] These diseases are most likely caused by an autoimmune response to bacteria which does not properly subside in the lining of the digestive tract.[48]

Based on an analysis of 245 cases of inflammatory bowel disease, the C8 Science Panel found a positive trend of increased risk with increasing cumulative exposure.[49] After a further breakdown of the data between ulcerative colitis and Crohn's disease, the C8 Science Panel concluded that a probable link exists between PFOA and ulcerative colitis.[50] Unfortunately, no other toxicology research had been done on PFOA's relationship with autoimmune disease, so the Science Panel was forced to make their judgment based entirely on their own studies.[51] The lack of these sorts

---

[40] *Know the facts about high cholesterol,* CENTERS FOR DISEASE CONTROL, https://www.cdc.gov/cholesterol/docs/consumered_cholesterol.pdf.

[41] Supra FN 39, at 6.

[42] Id.

[43] Id.

[44] Id.

[45] While this Petition for Rulemaking will only share the positive health links, it is important to note that the C8 Science Panel considered dozens of possible health risks, finding many health risks were not linked with PFOA. Thus the Panel did not just look for any potential health risk and find a way to link PFOA to that risk - the Panel was very thorough in its review of its own studies and studies conducted elsewhere. Id. at 8.

[46] *Probable Link Evaluation of Autoimmune Disease*, C8 SCIENCE PANEL, (July 30, 2012), http://www.c8sciencepanel.org/pdfs/Probable_Link_C8_Autoimmune_Disease_30Jul2012.pdf.

[47] Crohn's disease affects the entire digestive tract while ulcerative colitis affects the large intestine. See *Inflammatory bowel disease*, CENTERS FOR DISEASE CONTROL, https://www.cdc.gov/ibd/index.htm.

[48] Supra FN 45, at 4.

[49] Id. at 6.

[50] "The positive trend with PFOA exposure was found primarily for ulcerative colitis, for which there was a strong dose-response gradient. RRs by quartile of increasing exposure were 1.0, 1.89 (1.08 - 3.31), 2.58 (152 - 4.38), and 3.18 (1.84 - 5.51), p value test for trend <0.0001)." Id. at 6 - 7.

[51] Id.

of studies for even PFOA further emphasizes the need for greater toxicology research for all PFASs.

Thyroid Disease

The C8 Science Panel concluded that a probable link exists between PFOA exposure and thyroid disease.[52] A multitude of disorders can cause the thyroid gland to malfunction, but most commonly humans experience hypothyroidism and hyperthyroidism.[53] Hypothyroidism occurs when the body does not produce enough thyroid hormone, while hyperthyroidism is the opposite, where the body produces too much of the hormone.[54]

Prior to the C8 Panel's conclusions, two experimental studies had occurred on cynomolgus monkeys and rats, where scientists dosed the animals with PFOA and observed for changes in the thyroid hormone. In both studies, FT3 and TT3, forms of the thyroid hormone, dropped with increased serum levels of PFOA.[55] The C8 Panel also reviewed other epidemiologic studies conducted on the general population with mixed results.

When the C8 Panel conducted their studies on the people of the Mid-Ohio Valley, it found a "slight increasing trend of functional thyroid disease with increasing cumulative PFOA in serum."[56] Following additional studies, the C8 Panel found that the results were "consistent with a weak positive association between [thyroid] hormone levels and measured TSH, more apparent for women than for men (as this was found in relation to both modeled and measured PFOA)."[57] This measured increase in average TSH is "consistent with either an increased risk of hypothyroidism or a reduced risk for hyperthyroidism."[58]

Overall, the C8 Science Panel found the available evidence demonstrated a probable link between thyroid disease and PFOA. Consider the following:

> "We carefully considered how much weight to put on the different studies and analytic approaches, particularly whether it is appropriate to add up the pieces of supportive evidence despite their coming from different subsets of individuals or different indicators of thyroid disease. While each finding in isolation was not compelling, plausibly a result of chance or other errors, the presence of some independent pieces of evidence indicative of an association was not easily dismissed, despite a lack of coherence among them. Among the positive pieces, the strongest was the evidence of increased occurrence of medically validated thyroid disease (hyperthyroidism in women, hypothyroidism in men) with increasing measured PFOA exposure (2005 - 2006) in the prospective analyses (2005 - 2010). After taking into account the available evidence in its totality, despite inconsistencies in the evidence, the Panel concluded that there was evidence of a probable link between C8 and thyroid disease."[59]

---

[52] *Probable Link Evaluation of Thyroid disease*, C8 SCIENCE PANEL, (July 30, 2012), http://www.c8sciencepanel.org/pdfs/Probable_Link_C8_Thyroid_30Jul2012.pdf.

[53] Id. at 4.

[54] Id.

[55] Id. at 4 - 5.

[56] Id. at 7.

[57] Id.

[58] Id. at 9.

[59] Id. at 11.

Cancer

The C8 Science Panel found a probable link between PFOA exposure, testicular cancer, and kidney cancer.[60] Testicular cancer accounts for 0.5% of cancer cases, while kidney cancer accounts for 3.8%.[61] Previous studies on PFOA's relationship with cancer had found that it could cause "liver tumors, testicular tumors, and pancreatic tumors in rodents."[62] However, animal carcinogen data is only suggestive, and such relationships usually "aren't sufficiently consistent to allow reliable prediction of potential site(s) of carcinogenesis in humans from bioassay data in rodents."[63]

In 2008, a mortality study was performed on workers at the DuPont Washington Works plant, which originally found "no statistically significant ($p<0.05$) excesses for any cancers reported. However, numbers of specific cancers were small (8 liver, 11 pancreas, 12 kidney, 3 thyroid, 1 testis, 2 breast)."[64] A similar study covering 3M workers in Minnesota found no excess cancer deaths, and a study of the general population of Denmark did not find any links, either.[65]

However, when the C8 Science Panel conducted studies on the residents of the Mid-Ohio Valley and on the workers at the Washington Works plant, it found different results. When the Panel compared exposed water districts to non-exposed areas, the Panel found a positive trend with a p value of 0.002.[66] The trends for kidney cancer were less consistent, though one study found an increased rate of kidney cancer with a p value of 0.01.[67]

Following a string of inclusive studies, the C8 Science Panel developed a comprehensive cancer incident study which included 32,254 individuals.[68] This massive study, combined with the Panel's previous work, provided the following conclusions regarding PFOA's link to cancer:

> "For **testicular cancer**, there is evidence of a positive trend in risk across exposure groups, in some analyses, with the highest exposure group in both the internal analyses of the cohort study and the geographical cancer study showing estimated relative risks ranging from 3 to over 6 comparing the highest to lowest exposure groups. On the other hand there was little or no evidence of increasing risk in analyses from the same cohort compared with the U.S. population, and in the period after 2005, there were no new cases compared to about five expected. The high exposure group, where the higher risk was observed, comprise only six cases therefore there remains some uncertainty."[69]

---

[60] *Probable Link Evaluation of Cancer*, C8 SCIENCE PANEL, (April 15, 2012), http://www.c8sciencepanel.org/pdfs/Probable_Link_C8_Cancer_16April2012_v2.pdf.

[61] See *Cancer Stat Facts: Testicular Cancer*, NATIONAL CANCER INSTITUTE, https://seer.cancer.gov/statfacts/html/testis.html; See also *Cancer Stat Facts: Kidney and Renal Pelvis Cancer*, NATIONAL CANCER INSTITUTE, https://seer.cancer.gov/statfacts/html/kidrp.html.

[62] Supra FN 60, at 2.

[63] Id. at 3.

[64] Id.

[65] Id.

[66] Id. at 5.

[67] Id.

[68] Id. at 6.

[69] Id. at 10.

> "For **kidney cancer,** the worker mortality study conducted by the Science Panel showed a higher risk in the most highly exposed group compared to lower exposure groups among the workforce, but the risks were not elevated compared to the U.S. population. In the cohort study, there was a gradient of increasing risk with increasing exposure but most strongly in the analyses that included exposure up to the time of diagnosis. When the 10 years of exposure prior to diagnosis was excluded, the association was less evidence. No association was seen in the prospective analysis of cohort data, although the latter is limited by small numbers. In the geographic study some results suggested an increasing risk of kidney cancer with increasing exposure and others did not. The science panel considers that the excesses observed indicate a probable link between PFOA and kidney cancer."[70]

Pregnancy-induced Hypertension

The C8 Science Panel concluded that PFOA exposure is probably linked with pregnancy-induced hypertension.[71] Pregnancy-induced hypertension is a condition that can occur after the 20th week of pregnancy - a woman's blood pressure reaches levels considered "significantly elevated."[72] The condition can result in "reduced fetal growth and an increased risk of preterm birth."[73]

The C8 Science Panel analyzed four studies covering this particular condition and its relationship with PFOA, with two other studies looking at the relationship between PFOA and preeclampsia specifically. Additional toxicology studies performed on rodents also found reduced fetal growth and increased fetal death.[74]

The Panel found that "while few of the individual measures of association are strong or show clear evidence of increasing risk with increasing exposure across the full range of PFOA exposure....[and] while individually the observed associations could have alternative explanations, it is unlikely that the full pattern of findings could be explained by a series of hypothesized biases."[75] Furthermore, the odds for developing pregnancy-induced hypertension increased "for pregnancies that were closest in time to the measured serum PFOA values."[76]

Thus, the C8 Panel developed five probable links between health risks and PFOA:

(1) high cholesterol
(2) ulcerative colitis
(3) thyroid disease
(4) testicular and kidney cancer
(5) pregnancy-induced hypertension

---

[70] Id.

[71] *Probable Link Evaluation of Pregnancy Induced Hypertension and Preeclampsia*, C8 SCIENCE PANEL, (December 5, 2011), at 1, http://www.c8sciencepanel.org/pdfs/Probable_Link_C8_PIH_5Dec2011.pdf.

[72] Id.

[73] Preeclampsia, a form of pregnancy-induced hypertension, "can cause serious health problems for the mother and the fetus that can be alleviated only by delivering the fetus." Id.

[74] Id. at 5.

[75] Id.

[76] Id.

However, these conclusions were made almost four years prior to the Ei[illegible] Advisory. After four years of more scientific study, the EPA made the following [illegible] risk:

> "Taken together, the weight of evidence for human studies supports the conclusion that **PFOA exposure is a human health hazard.** At this time, EPA concludes that the human studies are adequate for use qualitatively in the identification hazard and are supportive of the findings in laboratory animals."[77]

However, the Health Advisory does not provide any mandatory regulations regarding PFOA for public water systems, waters of the United States, or for the manufacture or import of the substance. Even with these clear probable risks to human health, the EPA declined to promulgate the necessary regulations needed to protect human health and the environment.

ii. PFOA poses a risk to public water systems given its high concentrations discovered across the country.

PFOA's serious health risks are multiplied by its prevalence throughout U.S. public water systems. A combination of EPA data and other water monitoring data shows the location of PFOA public water system hotspots. The majority of PFOA data for public water systems was procured when PFOA and other PFASs[78] were listed on the EPA's Unregulated Contaminant Monitoring Rule ("UCMR").[79] While all public water systems serving 10,000 people or more were required to report data, only 800 "representative" public water systems with less than 10,000 people were required to monitor on the UCMR.[80]

The EPA has compiled the occurrence data for all unregulated contaminants monitored between 2013 and 2015 as part of the third UCMR.[81] While the EPA provides useful summary reports, it is difficult to visualize the full scope of PFOA inundation throughout America's public water systems using the agency's data. Fortunately, the Environmental Working Group in collaboration with the Social Science Environmental Health Research Institute of at Northeastern University has compiled all of the relevant data for PFOA into an easy to read map while also providing narratives for particular cases where a public water system measured a high concentration of

---

[77] Supra FN 19, at 30, emphasis added.

[78] In particular, the third UCMR measured perfluorooctanesulfonic acid (PFOS), perfluorooctanoic acid (PFOA), perfluorononanoic acid (PFNA), perfluorohexanesulfonic acid (PFHxS), perfluoroheptanoic acid (PFHpA), and perfluorobutanesulfonic acid (PFBS). *Third Unregulated Contaminant Monitoring Rule*, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, (December 9, 2016), https://www.epa.gov/dwucmr/third-unregulated-contaminant-monitoring-rule.

[79] See Id.

[80] Id.

[81] See *Occurrence Data for the Unregulated Contaminant Monitoring Rule*, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, (January 29, 2018), https://www.epa.gov/dwucmr/occurrence-data-unregulated-contaminant-monitoring-rule.

PFOA.[82] The Social Science Environmental Health Research Institute also has its own PFAS contamination site tracker that it regularly updates.[83]

In total, the Institute's analysis identifies 162 systems that found PFOA and/or PFOS.[84] However, these 162 sites only include locations that reported PFOA over 0.02 micrograms per liter or reported PFOS over 0.04 micrograms per liter. The EPA only required systems to report at those levels or higher. These reporting limitations make it difficult to accurately assess the full extent of exposure to PFASs, especially when certain organizations have advocated for drastically lower limitations, though such proposed limits will be discussed in further detail in the next section. This lack of comprehensive data is further complicated by the EPA's decision to only task 800 of the thousands of public water systems that serve less than 10,000 people with monitoring under the UCMR.

While the OEC could spend pages highlighting all of the serious cases of PFOA exposure identified by the Environmental Working Group, we will instead provide a few key examples of PFAS contamination that highlight this health crisis. We have already discussed the pollution that has occurred from the Washington Works facility in West Virginia along the Ohio River and briefly mentioned GenX pollution in North Carolina. But dozens of other examples exist, too, including the following stories.

Alabama

Following the release of the EPA's Health Advisory for PFOA, the Alabama Department of Public Health and the Alabama Department of Environmental Management worked together to assist public water systems that had detected high levels of PFOA and PFOS.[85] Alabama identified two systems in the state that needed to take action: The West Morgan-East Lawrence Water Authority, and the West Lawrence Water Co-op.[86] The agencies performed additional sampling and provided recommendations regarding the use of water in those systems, suggesting that "pregnant and breastfeeding mothers served by identified water systems consider using alternate sources of drinking water."[87]

A few months later, the Gadsden Water Works and Sewer Board in Alabama actually initiated a lawsuit against 32 carpet makers located near Dalton Georgia, "charging the companies with releasing potentially dangerous chemicals used in stain-resistant carpet into the river from which

---

[82] Bill Walker and Soren Rundquist, *Mapping a Contamination Crisis*, ENVIRONMENTAL WORKING GROUP, (June 8, 2017), https://www.ewg.org/research/mapping-contamination-crisis#4.

[83] See *PFAS Contamination Site Tracker,* SOCIAL SCIENCE ENVIRONMENTAL HEALTH RESEARCH INSTITUTE, https://pfasproject.com/pfas-contamination-site-tracker/.

[84] Supra FN 82.

[85] *Health Department modifies Health Advisories impacting north Alabama water systems*, Alabama Department of Public Health, (May 23, 2016), https://www.adph.org/news/assets/160523.pdf.

[86] *PFOS and PFOA in Drinking Water*, ALABAMA A&M & AUBURN UNIVERSITIES EXTENSION, (2016), http://www.aces.edu/pubs/docs/A/ANR-2326/ANR-2326.pdf.

[87] Supra FN 84.

Gadsden and nearby communities get their water supply."[88] The lawsuit specifically identified PFOA and PFOS as the culprits, noting samples "that showed 84 parts per trillion of PFOA...in one test and 82 parts per trillion of PFOA in another."[89] These measurements were above the 70 parts per trillion, or 0.07 micrograms per liter, that the EPA declared in their Health Advisory in 2016.

Minnesota

3M, a company that produced PFASs for decades similar to DuPont, maintains its "Cottage Grove" facility near Minneapolis, Minnesota. 3M did not remove PFASs from its wastewater before the sewage entered the Mississippi River.[90] PFASs may have also entered the environment through sludge disposed on site, from firefighting foams used in training exercises, or released into the air.[91] The Minnesota Department of Health also found, through environmental testing, "that the groundwater beneath the 3M Cottage Grove site is contaminated with PFOA, and other [PFASs] including perfluorooctane sulfonate (PFOS) and perfluorobutanoic acid (PFBA)."[92]

In addition to the Cottage Grove site, the Minnesota Department of Health believes other sources of PFASs in the region include the 3M-Woodbury Disposal Site, the 3M-Oakdale Disposal Site, and the Washington County Landfill at Lake Elmo.[93] Due to these detections of PFASs in the region, the Minnesota Department of Health tested residents for PFAS levels in their bloodstream, finding that concentrations "were higher than the averages for the general U.S. population."[94] Fortunately, when the residents that participated in the study drank treated water, their PFAS concentrations decreased over time.[95]

Just like in Alabama and in Ohio, plaintiffs pursued a lawsuit against 3M because of their contribution to PFAS pollution in public water systems.[96]

Michigan

While most Americans know of the Flint, Michigan water crisis regarding lead, many Americans probably do not know that the Flint River also had a problem with PFASs. In 2016, water sampling of the river found PFOA levels at 1.309 micrograms per liter and PFOS levels of .410

---

[88] Dave Flessner, *Lawsuit claims Dalton, Ga., carpet companies polluted Alabama drinking water with chemical linked to cancer*, TIMES FREE PRESS, (September 24, 2016), http://www.timesfreepress.com/news/business/aroundregion/story/2016/sep/24/lawsuit-dalton-ga-carpet-companies-polluted-a/388373/.

[89] 84 parts per trillion equals 0.084 micrograms per liter and 82 parts per trillion equals 0.082 micrograms per liter. Id.

[90] *3M Cottage Grove Facility*, MINNESOTA DEPARTMENT OF HEALTH, (June 2016), http://www.health.state.mn.us/divs/eh/hazardous/sites/washington/3Mcottagegrove.html.

[91] Id.

[92] Id.

[93] Id.

[94] Id.

[95] Id.

[96] Sharon Lerner, *Lawsuits charge that 3M knew about the dangers of its chemicals*, THE INTERCEPT, (April 11, 2016), https://theintercept.com/2016/04/11/lawsuits-charge-that-3m-knew-about-the-dangers-of-pfcs/.

micrograms per liter.[97] In addition to PFOA and PFOS, eleven other PFASs were identified in samples of the Flint River's water and fish populations.[98]

In northern Michigan, PFOA levels of 7.4 micrograms per liter were identified at a fire hydrant at the Wurtsmith Air Force Base.[99] On March 23, 2016, a number of different agencies held an open house to discuss the contamination of PFASs in the base's water supply, including the Michigan Department of Environmental Quality, Michigan Department of Health and Human Services, and the U.S. Air Force.[100] During that meeting, the agencies attributed the presence of PFASs to firefighting foam.[101]

New Jersey

In 2009, the DuPont Chambers Works facility region had dangerously high PFOA levels.[102] Even as the EPA had instituted a 0.4 micrograms per liter advisory level for PFOA, New Jersey had already instituted a more stringent regulatory standard of 0.04 micrograms per liter in a rule that also allowed the New Jersey Department of Environmental Protection to "require or provide for treatment" in the event a concentration exceeds that action level.[103] Wells located near the DuPont facility registered above even the EPA's 0.4 micrograms per liter requirement in 2008, clearly well above New Jersey's 0.04 micrograms per liter requirement.[104]

Montclair, New Jersey had three wells sampled in 2015 that resulted in PFOA measurements between .035 micrograms per liter and .048 micrograms per liter.[105] In response, the municipality installed carbon filtration systems, a technology that successfully removes PFOA from a water source.[106]

In 2016, a well in South Orange, New Jersey had PFOA levels of .058 micrograms per liter, above the New Jersey guideline in that year of 0.04 micrograms per liter.[107] The town argued against the PFOA exposure being a health threat to its citizens, saying that "Well #17 water represents only about 10% of the water introduced into the distribution system and it is blended

---

[97] *Flint, Michigan*, SOCIAL SCIENCE ENVIRONMENTAL HEALTH RESEARCH INSTITUTE, https://pfasproject.com/flint-michigan/.

[98] Id.

[99] *Oscoda Township, Michigan*, SOCIAL SCIENCE ENVIRONMENTAL HEALTH RESEARCH INSTITUTE, https://pfasprojec t.com/oscoda-township-michigan/.

[100] *Perflourinated Chemicals in Drinking Water Wells in Oscoda Township: Responses to Community Concerns as of June 6, 2016,* MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES, (June 6, 2016), https://www.mich igan.gov/documents/mdhhs/General_Questions_from_March_2016_Public_Meeting_Posted_527011_7.pdf.

[101] Id. at 3.

[102] *PFOA pollution in the vicinity of the DuPont Chambers Works Facility, Deepwater, Salem County, New Jersey*, DELAWARE RIVERKEEPER, (April 28, 2009), http://www.delawareriverkeeper.org/sites/default/files/resources/Lette rs/PFOA_pollution_in_the_vicinity_of_the_DuPont_Chambers_Works_Facility_4-28-09.pdf.

[103] Id.

[104] Id.

[105] *Montclair, New Jersey*, SOCIAL SCIENCE ENVIRONMENTAL HEALTH RESEARCH INSTITUTE, https://pfaspro ject.com/montclair-new-jersey/.

[106] Id.

[107] *South Orange, New Jersey*, SOCIAL SCIENCE ENVIRONMENTAL HEALTH RESEARCH INSTITUTE, https://pfasproje ct.com/south-orange-new-jersey/.

with other non-contaminated water prior to delivery to any customer....the water actually delivered to consumers likely has PFOA levels below the guidance limits."[108] Even if we accept that argument, this polluted drinking water well still illustrates the inundation of PFOA throughout the nation's water bodies and ground water.

New York

In 2005, the New York State Department of Environmental Conservation had data indicating that wells near the Taconic Plastics factory in Petersburgh, New York had PFOA levels as high as 152 micrograms per liter.[109] Residents who lived near the factory actually rented homes from the company, and the company had instructed residents not to drink tap water; the company provided both its workers and nearby residents bottled water to drink instead.[110]

A plastics manufacturing plant near Hoosick Falls, New York had a groundwater sample that revealed PFOA levels at 130 micrograms per liter - high on its own, but also seven times higher than a previous sample at the same site reaching 18 micrograms per liter.[111] Following this discovery of contamination, Taconic alerted the Department of Environmental Contamination who began testing near the factory again.[112] After discovering high PFAS contamination, the state provided the residents with bottled water.[113] For its part, Taconic has paid "to install carbon filter systems on private homes and a system for the municipal water supply."[114] New York declared PFOS a "hazardous substance" in 2016.[115]

Vermont

After the Vermont Department of Health established their PFOA advisory level as 0.02 micrograms per liter, three samples in Pownal, Vermont had PFOA concentrations of 0.026 and 0.027 micrograms per liter.[116] Following the discovered contamination, the Vermont Department of Environmental Conservation tested private drinking wells in a one-mile radius around the Warren Wire plant, the suspected source of the contamination.[117]

That PFOA discovery is only the tip of the iceberg in Vermont, however. A month prior to discovering contamination near Pownal, PFOA was also detected in North Bennington. Near a ChemFab factory, the Vermont environmental officials tested private wells and discovered levels of PFOA over 1 microgram per liter.[118]

---

[108] Id.

[109] *Rensselaer County and Petersburgh, New York*, SOCIAL SCIENCE ENVIRONMENTAL HEALTH RESEARCH INSTITUTE, https://pfasproject.com/rensselaer-county-and-petersburgh-new-york/.

[110] Id.

[111] Amanda Fries, *Hoosick Falls residents shocked by high PFOA test results*, TIMES UNION, (June 19, 2017), http://www.timesunion.com/7dayarchive/article/Hoosick-Falls-meeting-11231034.php.

[112] Supra FN 109.

[113] Id.

[114] Id.

[115] Id.

[116] Edward Damon, *Vermont will test Pownal wells for PFOA contamination*, THE BERKSHIRE EAGLE, (March 26, 2016), http://www.berkshireeagle.com/stories/vermont-will-test-pownal-wells-for-pfoa-contamination,191787.

[117] Id.

[118] Id.

New Hampshire

In 2014, the city of Portsmouth, New Hampshire shut down a well that serves the Pease International Tradeport because PFOS was found in the water source.[119] The officials investigating the well speculated that the concentrations found in the well resulted from firefighting foam used by the Air Force starting in the 1970s.[120] In 2014, the New Hampshire Department of Health and Human Services communicated to the public that "health officials don't know the health impacts - if any - from drinking water containing PFOS."[121]

Colorado

In 2016, two Colorado law firms filed class action suits due to PFAS contamination in El Paso County water systems.[122] After the EPA issued its Health Advisory in May 2016, the law firms pursued suits regarding drinking water systems with PFAS levels above the Health Advisory guidelines.[123] As defendants, the suits targeted companies like 3M that sold firefighting foam to a nearby Air Force base.[124] The PFAS Project references data that at one point, all 32 Security Water and Sanitation District municipal wells in El Paso County exceeded the 2016 EPA Health Advisory level, with one well having 1.37 micrograms per liter of PFAS.[125]

ii. PFOA and PFASs pose a risk to the environment due to their persistent nature and their high rates of accumulation in all Americans.

While the past historical concerns regarding PFOA and PFASs across the country should give anyone pause regarding the health risks of these substances, the most pressing risk regarding PFASs lies in the future. While long-chain PFASs like PFOA, PFOS, and PFNA pose the greatest risks, all PFASs threaten human health and the environment due to their persistent nature in the environment and the bloodstream of humans and animals. Furthermore, we simply do not know what will happen to human health if PFASs build up together in the blood stream, forming a toxic mixture whose individual components may or may not be dangerous individually.

PFOA has traits that make it particularly persistent in the environment. First, the molecule is quite mobile due to its ability to adsorb to particles in the air. Research in 2006 and 2012 identified PFOA in the Arctic and Antarctic regions of Earth.[126] PFOA is "resistant to hydrolysis, photolysis, volatilization, and biodegradation."[127] Two main methods exist to eliminate PFOA: either allow it to dissipate in water through dilution, advection, and absorption, or destroy it

---

[119] Jeff McMenemy, *Water contamination shuts down well at Pease*, SEACOAST ONLINE, (May 22, 2014), http://www.seacoastonline.com/article/20140522/NEWS/140529897.

[120] Id.

[121] Id.

[122] Jake Brownell, *A Closer Look at PFC Contamination in Southern El Paso County*, KRCC, (September 28, 2016), http://krcc.org/post/closer-look-pfc-contamination-southern-el-paso-county.

[123] Id.

[124] Id.

[125] *El Paso County, Colorado*, SOCIAL SCIENCE ENVIRONMENTAL HEALTH RESEARCH INSTITUTE, https://pfasproject.com/el-paso-county-colorado/.

[126] Supra FN 19, at 24.

[127] Id.

through municipal waste incineration of papers and textiles that contain the substance.[128] Of course, the latter option is not available when PFOA is discharged into water bodies.

When PFOA enters a biological organism, it spreads throughout body tissue with a tendency to accumulate in the liver, kidneys, lungs, heart, muscles, testes, and uterus.[129] The human body cannot metabolize PFOA, so health effects due to PFOA are the result of PFOA itself, not metabolites.[130] PFOA can transfer during pregnancy through the placenta and the amniotic fluid.[131] The half-life for PFOA in humans is 2.3 years based on studies of the Lubeck Public Services District in West Virginia and the Little Hocking Water Association in Ohio.[132] However, the half-life is much higher, at 3.8 years, for individuals who are exposed occupationally.[133]

Fortunately, data supports the proposition that PFOA levels in the general U.S. population is decreasing, with a mean of 5.2 micrograms per liter in 1999 to 2.1 micrograms per liter in 2012.[134] The EPA notes this decrease is most likely due to the reduction in emissions and phase-out of production of PFOA across the country.[135] However, this data does not take a deep dive into PFAS concentrations in humans as a whole; instead, it only looks at PFOA. PFOA has its own persistent characteristics, and long-chain PFASs will generally be more persistent than their short-chain counterparts, yet the Americans and the EPA cannot ignore the environmental risks of these other PFASs.

In 2015, the Danish Ministry of the Environment released "a literature review of information on human health effects and environmental fate and effect aspects of short-chain PFAS[s]."[136] The objectives of the study were twofold - the Danish government hoped to provide a holistic overview "of the human health and environmental fate and effects aspects of short-chained polyfluorinated substances introduced as alternatives to PFOS/PFOA and other long-chain PFAS," while also supporting "the Danish EPA's strategy on this substance group by providing background documentation in relation to further activities, including possible regulation."[137] The Danish government was particularly concerned that little published data existed on the properties of short-chain PFASs that could serve as alternatives to their long-chain counterparts.[138]

As of 2015, most of "the toxicokinetics and toxicity in humans for short-chain PFAS[s] [were] mainly investigated for PFHxS."[139] PFHxS has 6 carbon chains as opposed to the 8 carbon

---

[128] Id. at 24 - 25.
[129] Id. at 26.
[130] Id.
[131] Id.
[132] Id.
[133] Id.
[134] Id. at 27.
[135] Id.
[136] *Short-chain Polyfluoroalkyl Substances (PFAS)*, THE DANISH ENVIRONMENTAL PROTECTION AGENCY, (2015), https://www2.mst.dk/Udgiv/publications/2015/05/978-87-93352-15-5.pdf.
[137] Id. at 5.
[138] Id.
[139] Id. at 8.

chains of PFOA and PFOS.[140] While the health effects of PFHxS seem similar to that of PFOS, the Danish government concluded that it was impossible to evaluate any other short-chain PFAS from the available data.[141] This lack of available data represents the crux of the problem - companies across the United States and the world have begun using replacements for PFOA and other long-chain PFASs without sufficiently understanding the health and environmental effects of these short-chain siblings.

The Danish report does provide conclusions regarding the persistence of short-chain molecules, noting that "perfluorinated carboxylic and sulfonic acids, including short-chained [molecules], are not transformed/degraded by abiotic reaction mechanisms such [as] hydrolysis or photolysis in water to any appreciable extent."[142] While long-chained substances are more bioaccumulative than short-chained substances, all are "hydrophobic and lipophobic…[and] tend to bind to proteins and therefore are present rather in highly perfused tissues than in lipid tissue."[143] Generally, the Danish report emphasizes that for most short-chain PFASs, "there is virtually no available health-related information….[and] there is a general lack of specific experimental data….the environmentally relevant physico-chemical data identified appeared somewhat inconsistent and confusing."[144]

Another report from Europe discussed the effects of PFASs and their accumulation in the environment, coming to many of the same conclusions as the Danish report. In particular, the Concawe Soil and Groundwater Taskforce concluded the following:

> "It should be noted...that given the range of compounds present there is still uncertainty about their properties. In addition, low environmental concentration limits have been set for short-chain PFAS[s] (i.e. <C6 PFSA; <C7 PFCA) in many EU countries due to their persistence. Where possible, therefore, water containing PFAS-based fire-fighting foam residues should be captured for treatment and not discharged to the environment."[145]

The persistent nature of PFOA and other PFASs is potentially the most problematic of all of the environmental and health risks posed by these substances. As companies produce and use more and more PFASs, they perpetually inundate waters of the United States, public water systems, fish stocks, soil, and the atmosphere.

c. The Drinking Water Health Advisory issued by the United States Environmental Protection Agency in November 2016 inadequately protects Ohioans and Americans from the dangers of perfluorooctanoic acid and other perfluoroalkyl substances.

In the United States, recent literature from the American Chemical Society notes that public water systems inundated with PFASs can be predicted using spatial analysis. Specifically, "the

---

[140] Id. at 7.
[141] Id. at 8.
[142] Id.
[143] Id.
[144] Id. at 9.
[145] *Environmental fate and effects of poly- and perfluoroalkyl substances (PFAS)*, CONCAWE SOIL AND GROUNDWATER TASKFORCE, (June 2016), https://www.concawe.eu/wp-content/uploads/2016/06/Rpt_16-8.pdf.

number of industrial sites that manufacture or use these compounds, the number of military fire training areas, and the number of wastewater treatment plants are all significant predictors of PFAS detection frequencies and concentrations in public water supplies."[146] The researchers used the data acquired by the EPA during the third UCMR, and in doing so noted a few problems with the UCMR data.[147]

Because geospatial data for U.S. drinking water supplies is classified, the researchers found their ability to predict which supplies would contain elevated levels of PFASs restricted.[148] Additionally, their geospatial data lacked potentially important PFAS point sources "such as a wide range of industries, landfills, biosolids application, and other AFFF-impacted sites where relatively smaller volumes of AFFF were released."[149] Similarly, data on PFAS releases from smaller facilities can be withheld "as confidential business information."[150]

But most importantly:

> "Approximately 44.5 million U.S. individuals rely on private drinking water wells, and 52 million individuals rely on smaller public water supplies (<10,000 served). The UCMR3 program includes 0.5% testing incidence for smaller public water supplies and no testing of private wells, meaning that information about drinking water PFAS exposures is therefore lacking for almost one-third of the U.S. population."[151]

The EPA presented a robust analysis of the problem of PFOA, PFOS, and PFASs in its Health Advisory, but its data was largely incomplete because it lacked the water supplies of nearly a third of the U.S. population. These data analysis issues pale in comparison to the insufficiency of the actual level for lifetime exposure proposed in the Health Advisory.

In the 2016 Health Advisory, the EPA established a Health Advisory level of lifetime exposure of both PFOA and PFOS in drinking water at 70 parts per trillion, or 0.07 micrograms per liter.[152] However, many governmental entities have proposed maximum contaminant levels well below 0.07 micrograms per liter. The EPA has proposed a standard that it purports as cognizant of health risks, but really, this standard caters to the economic needs of businesses who still need PFOA, PFOS, and other PFASs for their bottom line. If the EPA were working to protect human health and the environment, it would instead adopt a more stringent standard, a standard that is binding instead of voluntary. The following subsection will illustrate the actions taken by other

---

[146] Xindi C. Hu, David Q. Andrews, Andrew B. Lindstrom, Thomas A. Bruton, Laurel A. Schaider, Philippe Grandjean, Rainer Lohmann, Courtney C. Carignan, Arlene Blum, Simona A. Balan, Christopher P. Higgins, and Elsie M. Sunderland, *Detection of Poly- and Perfluoroalkyl Substances (PFASs) in U.S. Drinking Water Linked to Industrial Sites, Military Fire Training Areas and Wastewater Treatment Plants*, 3 Environ. Sci. Technol. Lett. 2016, 344–350, https://pubs.acs.org/doi/pdf/10.1021/acs.estlett.6b00260.

[147] Id. at 4.

[148] Id.

[149] Id.

[150] Id.

[151] Id.

[152] *Fact Sheet: PFOA & PFOS Drinking Water Health Advisories*, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, (November 2016), https://www.epa.gov/sites/production/files/2016-06/documents/drinkingwaterhealthadvisories_pfoa_pfos_updated_5.31.16.pdf.

governments at both the state and international level that illustrate the clear failings of the EPA Health Advisory.

d. New Jersey, Minnesota, Vermont, New York, and the international community have taken significant stances against perfluorooctanoic acid and perfluoroalkyl substances that go beyond any actions taken by the United States Environmental Protection Agency.

Even as the federal EPA continues to fail to adequately regulate PFOA, a few states have taken direct action to protect their citizens. Similarly, countries across the world have acted to protect their own people from PFASs. The OEC summarizes below the choices made by a sampling of these governmental entities.

New Jersey
On October 3, 2017, New Jersey took steps to update its guidance on PFOA. The New Jersey Drinking Water Quality Institute conducted a "detailed evaluation of the relevant scientific information that is currently available;" based on that evaluation, it concluded that the Maximum Contaminant Level for PFOA should be 14 nanograms per liter, or 0.014 micrograms per liter, a level much lower than the federal level suggested in the EPA's Health Advisory.[153] What's more interesting is that New Jersey's guidance proposes an update to an already existing New Jersey requirement from 2007 that instituted a 0.04 microgram per liter level for PFOA, already lower than the non-binding standard later instituted by the EPA's Health Advisory in 2016.[154] New Jersey's guidance letter emphasized that the New Jersey Department of Environmental Protection planned on proposing 0.014 micrograms per liter for PFOA as a regulatory Maximum Contaminant Level, not just a guidance level for public water systems to take into consideration. In November, the state officially adopted 0.014 micrograms per liter as its MCL for PFOA.

Minnesota
Last October, Minnesota modified its guidance values for PFOA and PFOS. While non-binding, these guidance levels instruct local health officials to take action when PFOA concentrations are 0.035 micrograms per liter or when PFOS concentrations are 0.027 micrograms per liter.[155] The Minnesota Department of Health decided that it needed lower values than the EPA to "reflect new state-level analysis of the potential for mothers to pass along the chemicals to fetuses and nursing infants."[156]

Vermont
Vermont has taken action by performing blood samples and water samples in connection with a PFOA contamination that occurred in the State. For instance, in April 2016 the Health

---

[153] *Updated Drinking Water Guidance for Perfluorooctanoic Acid (PFOA)*, NEW JERSEY DEPARTMENT OF ENVIRONMENTAL PROTECTION, (October 3, 2017), http://www.nj.gov/dep/watersupply/pdf/pfoa_dwguidance.pdf.
[154] Id. See also *Determination of Perfluorooctanoic Acid (PFOA) in Aqueous Samples: Final Report*, NEW JERSEY DEPARTMENT OF ENVIRONMENTAL PROTECTION, (January 2007), http://www.nj.gov/dep/watersupply/pdf/final_pfoa_report.pdf.
[155] *MDH Current Activities: Perflurochemicals (PFCs) in Minnesota*, MINNESOTA DEPARTMENT OF HEALTH, (October 2017), http://www.health.state.mn.us/divs/eh/hazardous/topics/pfcs/current.html.
[156] Id.

Department offered PFOA to affected residents in North Bennington and Bennington.[157] In addition, Governor Scott signed S.10 on June 2, 2017, which required "any person who released PFOA to extend a municipal water line to all wells impacted by PFOA....[the bill] supplements the Agency [of Natural Resources'] existing authority and simplifies the process for ensuring responsible parties pay for costs to connect impacted homes to municipal water lines."[158]

New York

New York responded with force following a major PFOA contamination in Hoosick Falls, performing biomonitoring, blood-testing, cancer investigations, and water supply tests.[159] On March 3, 2017, New York released its final rule governing PFOA and PFOS, which added the two substances to the state's list of hazardous substances.[160] However, the amendment also continued to allow the use of firefighting foam that contains PFOA or PFOS.[161]

Ohio

While Ohio has not taken direct regulatory action regarding PFOA or other PFASs, in February 2018 Attorney General Mike DeWine filed a lawsuit against DuPont for their PFOA pollution in the Ohio River and nearby public water systems.[162] The Attorney General brought the action "to redress contamination by Defendant E. I. du Pont de Nemours and Company ("DuPont") of Ohio's natural resources with a *toxic substance, perfluorooctanoic acid*...which has caused significant damages and poses a significant ongoing threat to Ohio's natural resources and the citizens of Ohio."[163] With regards to the health risks of PFOA, the lawsuit states the following:

> "PFOA is a synthetic chemical compound that does not exist in nature. Human exposure to PFOA - even at very low levels - has been linked to kidney and testicular cancer, thyroid disease, pregnancy-induced hypertension and low birth weight, high cholesterol, and ulcerative colitis. PFOA is also a known toxicant and carcinogen in animals. The U.S. Environmental Protection Agency...has recognized that PFOA is extremely persistent in the environment, in both water and soil, and resistant to typical environmental degradation processes."[164]

If actual regulations existed on the books regarding PFOA and other PFASs, Ohio's Attorney General would not need to resort to lawsuits making claims of public nuisance, negligence, statutory nuisance, and trespass and rather could rely on the regulations mandating certain Water Quality Standards or requirements within NPDES permits.

---

[157] *PFOA in Drinking Water*, VERMONT HEALTH DEPARTMENT, (2018), http://www.healthvermont.gov/response/environmental/pfoa-drinking-water-2016.

[158] *PFOA Contamination Response: Community Update*, VERMONT AGENCY OF NATURAL RESOURCES, http://myemail.constantcontact.com/PFOA-Community-Update.html?soid=1105757924138&aid=zwcQOdpGobw.

[159] *PFOA in Drinking Water in the Village of Hoosick Falls and Town of Hoosick*, NEW YORK STATE DEPARTMENT OF HEALTH, (December 28, 2017), https://www.health.ny.gov/environmental/investigations/hoosick/.

[160] *Adoption of Final Rule: 6 NYCRR Part 597 (Hazardous Substances Identification, Release Prohibition, and Release Reporting*, NEW YORK STATE DEPARTMENT OF ENVIRONMENTAL CONSERVATION, (March 3, 2017), http://w ww.dec.ny.gov/regulations/104968.html.

[161] Id.

[162] See *State of Ohio, ex rel. DeWine v. E.I. Du Pont De Nemours and Co.*, Case No. 180T32, Court of Common Pleas, Washington County, Ohio, (February 8, 2018), Available at: http://www.ohioattorneygeneral.gov/Files/Briefing-Room/News-Releases/Environmental-Enforcement/2018-02-08-DuPont-Complaint.aspx

[163] Id. at 1 - 2.

[164] Id. at 2.

The Madrid Statement on Poly- and Perfluoroalkyl Substances (PFASs)
Developed and signed by scientists and professionals from across the world, the Madrid Statement communicates the scientific community's concern regarding the dangers of PFASs.[165] The Madrid Statement calls for the following actions from governments:

1. "Enact legislation to require only essential uses of PFASs, and enforce labeling to indicate uses.
2. Require manufacturers of PFASs to
    a. conduct more extensive toxicological testing,
    b. make chemical structures public,
    c. provide validated analytical methods for detection of PFASs, and
    d. assume extended producer responsibility and implement safe disposal of products and stockpiles containing PFASs.
3. Work with industry to develop public registries of products containing PFASs.
4. Make public annual statistical data on production, imports, and exports of PFASs.
5. Whenever possible, avoid products containing, or manufactured using, PFASs in government procurement.
6. In collaboration with industry, ensure that an infrastructure is in place to safely transport, dispose of, and destroy PFASs and PFAS-containing products, and enforce these measures."[166]

Similarly, the Madrid Statement calls for actions from chemical manufacturers:

1. "Make data on PFASs publicly available, including chemical structures, properties, and toxicology.
2. Provide scientists with standard samples of PFASs, including precursors and degradation products, to enable environmental monitoring of PFASs.
3. Work with scientists and governments to develop safe disposal methods for PFASs.
4. Provide the supply chain with documentation on PFAS content and safe disposal guidelines.
5. Develop nonfluorinated alternatives that are neither persistent nor toxic."[167]

Finally, the Statement calls for product manufacturers to take action steps to:

1. "Stop using PFASs where they are not essential or when safer alternatives exist.
2. Develop inexpensive and sensitive PFAS quantification methods for compliance testing.
3. Label products containing PFASs, including chemical identity and safe disposal guidelines.
4. Invest in the development and use of nonfluorinated alternatives."[168]

The Madrid Statement cites dozens of sources regarding the danger of PFASs and includes the signatures of well over a hundred scientists.

---

[165] *The Madrid Statement on Poly- and Perfluoroalkyl Substances (PFASs)*, 123 Environmental Health Perspectives 5, (May 1, 2015), https://ehp.niehs.nih.gov/wp-content/uploads/123/5/ehp.1509934.alt.pdf.
[166] Id. 1 - 2.
[167] Id. at 2.
[168] Id.

European Union

On June 14, 2017, the European Union took the first steps to regulate PFOA, "its salts, and certain related substances."[169] The EU made the following conclusion:

> "The Commission concluded that an unacceptable risk to human health and the environment from the manufacture, use or placing on the market of PFOA, its salts and PFOA-related substances on their own, as a constituent of other substances, in mixtures and in articles. The Commission considers that those risks need to be addressed on a Union wide basis."[170]

While there are a few exceptions to the regulation, generally speaking PFOA and its salts will be completely prohibited by the EU after July 4, 2020.[171]

e. Technology already exists for public water systems to protect their water sources from perfluorooctanoic acid, and that same technology could apply to companies that could potentially emit PFOA or PFASs into America's waterways.

When proposing the regulation of a contaminant, it helps when technologies exist that public water systems and point sources can use to protect drinking water from the contaminant, or that removes the contaminant from discharges into the waters of the United States. In the case of PFOA, public water systems along the Ohio River have already experimented with methods that protect their residents from the contaminant.[172] In addition, New Jersey and the Water Research Foundation have both provided recommendations on how to treat PFASs in drinking water.[173]

Following the contamination of water supplies along the Ohio River by PFOA from the Washington Works DuPont plant, the Lubeck Public Service District and the Little Hocking Water Association "began routine treatment with granular activated carbon to remove PFOA from the potable water supply."[174] These public water systems needed to find a way to treat their water; even though DuPont reduced their PFOA emissions at the Washington Works plant by 99% between 2000 and 2006, groundwater supplies remained contaminated with PFOA when the public water systems began their filtration efforts.[175]

---

[169] *EU Regulates PFOA and Related Substances Under Reach*, SAFEGUARDS, (June 23, 2017), http://www.sgs.com/en/news/2017/06/safeguards-09717-eu-regulates-pfoa-and-related-substances-under-reach.

[170] *Commission Regulation (EU) 2017 | 1000*, (June 13, 2017), L 150/14, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R1000&from=EN.

[171] Supra FN 170.

[172] See Scott M. Bartell, Antonia M. Calafat, Christopher Lyu, Kayoko Kato, P. Barry Ryan, and Kyle Steenland, *Rate of Decline in Serum PFOA Concentrations after Granular Activated Carbon Filtration at Two Public Water Systems in Ohio and West Virginia*, Environ Health Perspect 118:222–228 (February 2010), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2831921/pdf/ehp-118-222.pdf.

[173] See *Recommendation on Perfluorinated Compound Treatment Options for Drinking Water*, New Jersey Drinking Water Quality Institute, (June 2015), http://www.nj.gov/dep/watersupply/pdf/pfna-pfc-treatment.pdf; See also Eric R. V. Dickenson and Christopher Higgins, *Treatment Mitigation Strategies for Poly- and Perfluoroalkyl Substances*, WATER RESEARCH FOUNDATION, (February 2016), http://www.waterrf.org/ExecutiveSummaryLibrary/4322_ProjectSummary.pdf.

[174] Supra FN 172.

[175] Id.

Prior to treatment efforts, the Little Hocking Water Association had PFOA concentrations that ranged from 1.9 to 4.9 nanograms per milliliter, or approximately 0.0019 to 0.0049 micrograms per liter.[176] These levels were already far below the EPA advisory levels at that time and even today, yet these water systems still chose to reduce concentrations further, most likely to reduce lifetime buildup of the PFOA in their residents. Following treatment, PFOA concentrations dropped drastically, reaching a nearly unquantifiable level, or less than 0.016 nanograms per milliliter.[177] The Little Hocking Water Association replaces their carbon every three months in an effort to ensure there are "no detectable levels" of PFOA and related compounds in the water.[178]

A granulated activated carbon treatment method works by adsorbing molecules to the carbon.[179] The effectiveness of the method depends heavily on how many contaminants compete to adsorb to the carbon, but the New Jersey Drinking Water Quality Institute estimates that for PFNA, PFOA, and PFOS these activated carbon filtration systems reduce concentrations in water supplies by more than 90%.[180] Costs of the granulated carbon treatment method depends heavily "on the level of contaminant in the source water as well as the presence and concentration of other contaminants that compete for carbon surface area....in addition to capital costs...disposal of exhausted carbon is also a cost consideration."[181]

In addition to the Little Hocking Water Association, other water treatment facilities have installed this technology such as the cities of Oakdale, Minnesota and Penn's Grove, New Jersey. In 2006, Oakdale installed ten granulated activated carbon filters into a plant with a capacity to treat 2,000 gallons of water per minute.[182] The technology cost $3,000,000 and has annual operating costs of $25,000.[183] The Penn's Grove system, operated by New Jersey American Water, installed a granulated activated carbon system that cost $12.2 million with an annual cost of $80,000.[184] However, the treatment for PFOA "did not reach 50% breakthrough even after treating more than 231,666 Kgal."[185] Fortunately, New Jersey American Water had better success with the granulated activated carbon filtration in the Logan System Birch Creek, where PFOA levels of 33 to 60 nanograms per liter were reduced below 5 nanograms per liter after installation.[186]

While most public water systems have focused on treatment systems for long-chain PFASs like PFOA, PFNA, or PFOS, the Water Research Foundation has conducted research on treating the whole class of PFASs. Specifically, the stated goal of their study was to "evaluated the ability of

---

[176] Id.
[177] Id.
[178] *Recommendation on Perfluorinated Compound Treatment Options for Drinking Water*, NEW JERSEY DRINKING WATER QUALITY INSTITUTE, (June 2015), at 4 - 5, http://www.nj.gov/dep/watersupply/pdf/pfna-pfc-treatment.pdf.
[179] Id. at 3.
[180] Id.
[181] Id. at 4.
[182] Id. at 5.
[183] Id.
[184] Id.
[185] Id.
[186] Id. at 5 - 6.

a wide spectrum of full-scale water treatment techniques to remove PFASs from contaminated raw water or potable reuse sources to protect humans from this important route of exposure."[187] The project measured the levels of 23 PFASs, including "9 perfluorocarboxylic acids (PFCAs), 4 perfluorosulfonic acids (PFSAs), perfluorooctane sulfonamide (FOSA), 2 perfluorosulfonamidoacetic acids, 3 flurotelomer unsaturated carboxylic acids and 3 fluorotelomer sulfonates."[188]

The project concluded that granulated activated carbon treatments "were more effective at removing long-chain PFASs and PFSAs than PFCAs."[189] However, the most effective treatment method was not granulated activated carbon or the other common treatment technology, flat-sheet membranes; reverse osmosis "demonstrated significant removal for all the PFASs, including the smallest PFAS [included in the study], perfluorobutanoic acid."[190] Perfluorobutanoic acid has 4 carbon links as opposed to PFOA's 8 carbon links.[191]

Reverse osmosis is more costly than granulated activated carbon filtration, so the Water Research Foundation recommends the use of reverse osmosis only for public water systems that have high concentrations of short-chain PFASs.[192] But the research demonstrates that treatment techniques exist for both long-chain and short-chain PFASs. Not only can public water systems (or point sources) install technology that protects against PFOA, they can install technology that protects against all PFASs.

Most importantly, if public water systems can install technology that treats water before it is sent to its customers, emitters of PFASs can install that technology too as pollutants are discharged into water bodies. At the very least, the cost of installing this technology should not be on the shoulders of public water systems, especially public water systems under 10,000 residents. While solutions to this cost problem are beyond the scope of this Petition, many options exist for the EPA to utilize to ensure the privilege of protecting our water supplies from PFOA and PFASs is given to the appropriate parties.

III. The OEC requests the following rules, each of which would regulate PFOA and PFASs.

Therefore, based on the science explained above and in accordance with the laws outlined below, the OEC proposes specific regulations under the SDWA, the CWA, and TSCA that would regulate both PFOA and all PFASs. While the OEC recognizes the comprehensive nature of this request, the OEC also emphasizes the need for comprehensive protection of human health and

---

[187] Eric R. V. Dickenson and Christopher Higgins, *Treatment Mitigation Strategies for Poly- and Perfluoroalkyl Substances*, WATER RESEARCH FOUNDATION, (February 2016), at 2, http://www.waterrf.org/ExecutiveSummaryLibrary/4322_ProjectSummary.pdf.

[188] Id.

[189] Id.

[190] Id. at 3.

[191] See *Perfluorobutanoic Acid*, ALS ENVIRONMENTAL, (Accessed February 20, 2018), http://www.caslab.com/Perfluorobutanoic-Acid-3.php5.

[192] Id.

the environment. The CWA establishes that "it is the national policy that the discharge of toxic pollutants in toxic amounts be prohibited."[193] It is in an effort to achieve this national policy and other similar policies that the OEC proposes the following rules. In this section, we briefly state each proposed rule along with a short justification for the proposed rule. Sections IV, V, and VI provide the in-depth legal analysis required to justify the promulgation of these rules. For an example of what potential language might look like for any of these proposed Rulemakings, see Attachment I.

a. The EPA should develop Water Quality Criteria for PFOA at 0.014 micrograms per liter of water.

The Clean Water Act tasks the EPA with the promulgation of Water Quality Criteria that the states use in developing their Water Quality Standards and other rules that protect Waters of the United States and of the several States. Based on the conclusions made by states like New Jersey, the OEC proposes Water Quality Criteria of 0.014 micrograms per liter. This value will ensure that water bodies inundated with PFOA will receive the necessary treatment to protect human health and the environment and regulate future discharges of PFOA.

b. The EPA should develop Water Quality Criteria for PFASs at 0.07 micrograms per liter of water.

The OEC proposes that the EPA promulgate Water Quality Criteria that limits PFASs to a maximum concentration of 0.07 micrograms per liter of water in any particular water body. Thus, in a situation where PFOA does not reach over 0.014 micrograms per liter, yet collectively all PFASs have inundated a water body at over 0.07 micrograms per liter, the water body would still receive the necessary protections to halt the potential collective harm from these substances.

c. The EPA should develop a national Water Quality Standard for the Ohio River that accounts for the high levels of PFOA and PFASs in that watershed.

Because the Ohio River has been seriously harmed by PFOA and other PFASs over the past half century, the EPA should take immediate action and promulgate a national Water Quality Standard that includes a 0.014 microgram per liter limitation for PFOA and 0.07 micrograms per liter for all PFASs. The Ohio River and its tributaries cannot wait for the States or a regional organization such as the Ohio River Valley Water Sanitation Commission (ORSANCO) to take the necessary steps to protect the Ohio River from PFOA and PFASs.

d. The EPA should develop a Primary Drinking Water Regulation for PFOA at 0.014 micrograms per liter.

The OEC believes that the 0.014 micrograms per liter limitation proposed by the EPA in its Health Advisory is insufficient to adequately protect human health and the environment. Instead, the EPA should promulgate a Primary Drinking Water Regulation for PFOA that requires a public water system to take action if it has levels of PFOA over 0.014 micrograms per liter. This

[193] 33 U.S.C. §1251(a)(3).

lower threshold for action will ensure public water systems act before PFOA levels reach dangerous levels.

e. The EPA should develop a Primary Drinking Water Regulation for PFASs at 0.07 micrograms per liter.

The OEC proposes a Primary Drinking Water Regulation for PFASs that, at 0.07 micrograms per liter, would require action by a public water system. 0.07 micrograms per liter matches the original number proposed by the EPA for PFOA in its Health Advisory, but instead would cover all PFASs. This regulation would ensure that if a public water system becomes inundated with a multiplicity of PFASs, it would take action with the necessary treatment techniques.

f. The EPA should ban PFOA under TSCA, rather than continue with voluntary cooperation from businesses under the Stewardship Program.

Reasonably available information has highlighted PFOA to be a serious health concern due to its propensity to stay in the environment and in the human body for long periods of time. However, the voluntary curbing of PFOA use is not adequate, and it is imperative for the EPA to stop the manufacturing of PFOA in light of known health impacts and known alternatives for the substance. The OEC proposes, therefore, that the Administrator, within 90 days, issue a rule prohibiting the manufacture, processing, and distribution in commerce of PFOA because it presents an unreasonable risk to human health and the environment.

g. The EPA should require comprehensive testing of all PFASs under Section 4 of TSCA so businesses and the public know which PFASs cause an unreasonable risk to human health and the environment.

Current information on PFASs shows that they may pose unreasonable risks to human health and the environment. We must know more about PFASs in order to fully protect the American people. Therefore, the OEC proposes that the EPA direct a §4 testing order for PFASs focused on drinking water exposure pathways and to all persons who manufacture, intend to manufacture, process, or intend to process PFASs. At a minimum, EPA should direct this order to the manufacturers and processors who have used or plan to use PFASs as PFOA alternatives.

IV. The EPA should regulate PFOA and PFASs under the CWA.

33 U.S.C. §1251 spells out the purpose of the CWA, emphasizing seven specific goals, the first three of which are of import to this Petition for Rulemaking:

> (1) "it is the national goal that the discharge of pollutants into the navigable waters be eliminated by 1985;
>
> (2) it is the national goal that wherever attainable, an interim goal of water quality which provides for the protection and propagation of fish, shellfish, and wildlife and provides for recreation in and on the water be achieved by July 1, 1983; [and]

(3) it is the national policy that the discharge of toxic pollutants in toxic amounts be prohibited."[194]

While the United States failed to achieve these goals by the timelines stated in 1972, the substantive purposes remain the same. The United States has a national goal to eliminate the discharge of pollutants into navigable waters, achieve water quality suitable for aquatic life and recreation, and prohibit the discharge of toxic pollutants in toxic amounts. With these policies in mind, the OEC hereby proposes its Petition for Rulemaking regarding PFOA and PFASs under the Clean Water Act.

a. The Administrator of the EPA has the authority to establish Water Quality Criteria and a Water Quality Standard for the Ohio River under 33 U.S.C. §1313 and 1314.

The OEC has two specific requests for the EPA under the CWA which are separate from its requests under the TSCA and the SDWA. First, the OEC requests that the Administrator develop and publish Water Quality Criteria that reflects the latest scientific knowledge on the effects of PFOA and PFASs, as pursuant to 33 U.S.C. §1314(a). Second, the OEC requests that the Administrator prepare and make public regulations setting forth a Water Quality Standard for the Ohio River that includes a specific limitation on the levels of PFOA and PFASs, pursuant to 33 U.S.C. §1313(c)(4)(B).

The Administrator not only can promulgate these regulations; the Clean Water Act mandates that he must promulgate these regulations. Otherwise, the EPA is in ongoing violation with the requirements of the CWA.

i. The Administrator has the duty to publish Water Quality Criteria that informs the public of all effects a pollutant may have upon health and welfare.

The CWA envisioned a robust federalist system of regulation, where the EPA publishes Water Quality Criteria that assist state agencies in their direct regulation of pollution into water bodies. While states, for the most part, do the lion's share of water body protection, the EPA plays an important role in guiding those state agencies with suggested "Water Quality Criteria." The CWA states:

> "The Administrator...shall develop and publish...(and from time to time thereafter revise) criteria for water quality accurately reflecting on the latest scientific knowledge on the kind and extent of all identifiable effects on health and welfare...which may be expected from the presence of pollutants in any body of water, including ground water."[195]

In addition to the requirement regarding Water Quality Criteria, the Administrator must publish "information" that explains how to "restore and maintain the chemical, physical, and biological integrity of all navigable waters, [and] ground waters."[196] This information also includes data

---

[194] 33 U.S.C. §1251(a)(1) - (3).
[195] 33 U.S.C. §1314(a)(1).
[196] 33 U.S.C. §1314(a)(2).

"necessary for the protection and propagation" of aquatic wildlife, "measurement and classification of water quality," and "identification of pollutants" that can be measured for TMDL purposes.[197]

In practice, the EPA provides "Water Quality Criteria" for aquatic life, biology, human health, microbes and recreational activity, and suspended and bedded sediment.[198] For instance, the EPA has promulgated Water Quality Criteria for arsenic, proposing 0.018 micrograms per liter of water and fish consumption, or 0.14 micrograms per liter of fish consumption.[199]

The states as well as tribal governments use the criteria to develop their Water Quality Standards, so it is of paramount importance that the federal government provides the most robust set of data possible that fulfills the CWA's principal purpose: "restore and maintain the chemical, physical, and biological integrity of the Nation's waters."[200] If the Administrator does not develop Water Quality Criteria for PFOA, then the Administrator has acted in an arbitrary and capricious manner and abused his mandate to develop Water Quality Criteria that protects our nation's water resources. The science shows that PFOA poses a risk to human health, and the EPA must provide Water Quality Criteria that protects human health.

ii. The Administrator has the duty to publish Water Quality Standards that satisfy the requirements of the CWA.

While individual states normally develop Water Quality Standards for particular water bodies by stating specific designated uses through either numeric or narrative criteria for those water bodies, the Administrator of the EPA has the authority to develop Water Quality Standards for navigable waters. The Administrator's power in this regard is defined as follows:

> "Promptly prepare and publish proposed regulations setting forth a revised or new Water Quality Standard for the navigable waters involved in any case where the Administrator determines that a revised or new standard is necessary to meet the requirements of this chapter."[201]

Normally, water bodies in Ohio receive their Water Quality Standards from the Ohio Environmental Protection Agency ("OEPA"). For example, The OEPA gave the Scioto River drainage basin has hundreds of different use designations for different portions of the river and different streams contained within the watershed. At River Mile 33.6, the Scioto River is designated as a "Warmwater Habitat,"[202] while at River Mile 132.3 to Greenlawn Dam, the river

---

[197] Id.

[198] See *Basic Information on Water Quality Criteria*, UNTED STATES ENVIRONMENTAL PROTECTION AGENCY, (July 5, 2017), https://www.epa.gov/wqc/basic-information-water-quality-criteria.

[199] See *National Recommended Water Quality Criteria - Human Health Criteria Table*, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, (October 10, 2017), available at: https://www.epa.gov/wqc/national-recommended-water-quality-criteria-human-health-criteria- table.

[200] 33 U.S.C. §1251(a).

[201] 33 U.S.C. §1314(c)(4)(B).

[202] A "warmwater habitat," is described by the Ohio EPA as satisfying the "baseline regulatory requirements in line with Clean Water 'fishable goal' expectations." *Summary of Ohio's Beneficial Use Designations*, OHIO ENVIRONMENTAL PROTECTION AGENCY, (April 2004), http://www.epa.ohio.gov/portals/35/wqs/designation_summary.pdf.

is designated as a "Modified Warmwater Habitat."[203] Water Quality Standards also implement specific limitations on the concentrations of substances in the water bodies; those numbers are developed in accordance with TMDLs created for the watershed.

These Water Quality Standards are then approved by the EPA. If the EPA believes that a Water Quality Standard proposed by a state agency fails to satisfy the requirements of the CWA, it may reject the standard and order the state agency to create a new standard. If the state agency fails to satisfy the EPA's request, the EPA may promulgate a Water Quality Standard that supersedes the state agency's previous failed rulemaking.[204]

Ohio also implements Water Quality Criteria at Ohio Administrative Code §§3745-1-33, 3745-1-34, 3745-1-35, and 3745-1-37 that are then used when developing Water Quality Standards for specific water bodies. Ohio has not promulgated its own Water Quality Criteria for PFOA.

EPA Administrators, using their authority under 33 U.S.C. §1314(c)(4)(B), have developed Water Quality Standards for a number of water bodies when state agencies have failed to adequately protect those water bodies. In 2004, the EPA promulgated Water Quality Standards for the state of Ohio regarding levels of bacteria in Lake Erie due to a statutory deadline the OEPA failed to meet.[205] Similarly, the EPA has recently proposed a regulation that would establish numeric criteria for the San Francisco Bay and Delta in California for selenium.[206]

As this Petition for Rulemaking shows, PFOA and PFASs represent a danger to human health and the environment in violation of the CWA. This Petition also shows that the Ohio River and other associated water bodies are seriously affected by these substances. The CWA grants the Administrator authority to promulgate Water Quality Standards when he "determines that a revised or new standard is necessary to meet the requirements of this chapter."[207]

b. The Administrator of the EPA should grant the relief requested under the CWA because PFOA and PFASs harm human health and the environment.

As outlined in §2, PFOA and PFASs pose a serious risk to human health and the environment. PFOA in particular is linked with the following health conditions:

(1) high cholesterol
(2) ulcerative colitis

---

[203] A "modified warmwater habitat," is described by the Ohio EPA as a less restrictive requirement "for dissolved oxygen and ammonia," and "may result in less restrictive wastewater treatment requirements." Id.

[204] Specifically, the statute states: "The Administrator shall promptly prepare and publish proposed regulations setting forth a revised or new Water Quality Standard for the navigable waters involved...if a revised or new Water Quality Standard submitted by such State...for such waters is determined by the Administrator not to be consistent with the applicable requirements of this chapter." 33 U.S.C. §1313(c)(4)(A).

[205] See *Final Water Quality Standards for Coastal and Great Lakes Recreation Waters*, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, (March 17, 2017), available at https://www.epa.gov/beach-tech/final-water-quality-standards-bacteria-rule-coastal-and-great-lakes-recreation-waters.

[206] See *Water Quality Standards Regulations: California*, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, (October 24, 2017), https://www.epa.gov/wqs-tech/water-quality-standards-regulations-california.

[207] 33 U.S.C. §1314(c)(4)(B).

(3) thyroid disease
(4) testicular and kidney cancer
(5) pregnancy-induced hypertension

Additionally, PFASs pose a risk due to the lack of sufficient knowledge regarding their potential health risks. While a massive body of knowledge has been compiled regarding PFOA through the efforts of many researchers and the C8 Science Panel, many PFASs have little to know toxicology research. Thus, even while the EPA does not know all of the health effects of these substances, it continues to allow polluters to discharge PFASs into the waters of the United States. The EPA is allowing a potentially toxic mixture of thousands of substances to form in our waterways without the knowledge to definitively state that such mixture is safe.

If PFASs degraded in the environment quickly, these discharges may not be much of an issue. However, PFASs are incredibly stable and remain in the environment for decades. The accumulation of high levels of PFASs may have untold long-term consequences for ecosystems and for human health. If the United States is to satisfy the purpose of the CWA, it must act and protect the nation's water bodies from PFOA and all PFASs. It can accomplish this goal by promulgating Water Quality Criteria, as well as Water Quality Standards for valuable water bodies like the Ohio River.

c. The OEC proposes the following regulations as the Water Quality Criteria for PFOA and PFASs.

The OEC, in an effort to assist the EPA in the important task of protecting human health and the environment, wishes to provide recommended text for promulgation as "Water Quality Criteria" and "Water Quality Standards" for the Ohio River. The OEC believes that these suggestions are simultaneously reasonable, non-arbitrary, and justified in light of the evidence presented establishing the danger of PFOA and PFASs. For a clear statement of the proposed regulations, see Attachment 1.

i. The OEC petitions the Administrator of the EPA to issue Water Quality Criteria for PFOA that limits its presence in water bodies to 0.014 micrograms per liter of water.

Through its authority under the CWA at 33 U.S.C. §1314(a)(1), the EPA should regulate PFOA. The OEC proposes 0.014 micrograms per liter as the human health Water Quality Criteria for PFOA for consumption of water and organism, and consumption of an organism only. The 0.014 micrograms per liter concentration is calculated based on the action taken by New Jersey to regulate PFOA in 2017. New Jersey became the first state to issue a maximum contaminant level for PFOA at 0.014 micrograms per liter for public water systems due to the substance's health risks.[208] For the sake of consistency, the EPA should promulgate Water Quality Criteria identical to drinking water standards. When a public drinking water system has a legal requirement to act, so should polluters.

---

[208] *Christie Administration Takes Action to Enhance Protection of New Jersey's Drinking Water*, NEW JERSEY DEPARTMENT OF ENVIRONMENTAL PROTECTION, (November 1, 2017), http://www.nj.gov/dep/newsrel/2017/17_0104.htm.

The OEC readily expects the EPA to reject 0.014 micrograms per liter in favor of 0.07 micrograms per liter, the number used in the agency's Health Advisory. However, New Jersey provided specific reasons for preferring 0.014 micrograms to the EPA's suggested value, or even the state's previous guidance level of 0.04 micrograms per liter. New Jersey's Department of Environmental Protection determined that it needed to account for uncertainty factors of effects that occur at low doses:

> "A Health-based MCL protective for increased relative liver weight was derived based on a study in which male mice were exposed to PFOA for 14 days....For increased relative liver weight, the Target Human Serum Level is 14.5 ng/ml and the Reference Dose is 2 ng/kg/day. This Target Human Serum Level and Reference Dose incorporate uncertainty factors to protect sensitive human subpopulations, to account for toxicodynamic differences between human and experimental animals, and to protect for more sensitive endpoints that occur from developmental exposures (delayed mammary gland development, persistent hepatic toxicity, and others). Default values for drinking water exposure assumptions (2 L/day water consumption; 70 kg body weight) and Relative Source contribution factor (20%) were used to develop a Health-based MCL of 14 ng/L based on the reference Dose for increased relative liver weight.
>
> A cancer slope factor of 0.021 $(mg/kg/day)^{-1}$ was developed based on increased incidence of testicular tumors in a chronic rat study. >This slope factor was used to develop a Health-based MCL protective for cancer effects at the 1×10^{-6} (one in one million) lifetime cancer risk level of 14 ng/L, identical to the Health-based MCL based on non-cancer endpoints."[209]

While the OEC proposes these same numeric values under the SDWA, it is essential that these numeric values also apply under the CWA to effectively protect human health and the environment at every step of the process. If the EPA can protect water bodies before contaminants ever reach public water systems, then local public water systems can save money because they do not need to install treatment technology. By developing a regulation under the CWA, the agency will place the burden of treatment upon the point sources themselves, rather than primarily upon drinking water systems. Further, Water Quality Criteria will ensure that organisms living in water bodies are protected from PFOA too. While a National Safe Drinking Water Regulation protects citizens from consuming water with PFOA, it does not protect against ingesting PFOA through fish consumption.

ii. The OEC petitions the Administrator of the EPA to issue Water Quality Criteria for PFASs that limits its presence in water bodies to 0.07 micrograms per liter of water.

Similarly, through its authority under the CWA at 33 U.S.C. §1314(a)(1), the EPA should regulate PFASs. If a particular water body becomes too inundated with PFASs, there must be a burden placed upon point sources to install appropriate technology to rectify the problem.

As explained in §2, the inadequate literature published on most PFASs poses a serious health risk due to the serious uncertainty of what a combination of many different PFASs in the bloodstream might cause. The EPA should embrace the precautionary principle and in the absence of certain

[209] Supra FN 153, at 4.

science take action to protect human health and the environment. We cannot allow a potentially toxic mixture to form in our waterways nor the bloodstreams of U.S. citizens.

To that end, the OEC proposes that the EPA use 0.07 micrograms per liter as the values for the consumption of water and organism, and consumption of an organism only. These values should sufficiently protect human health and the environment, especially in accordance with the EPA's Health Advisory on PFOA and PFAS. Whenever a combination of PFOA, PFOS, and other long-chain PFASs reaches 0.07 micrograms per liter in a water body, states would need to promulgate a TMDL or take other necessary corrective action.

With a value of 0.07 micrograms per liter, the EPA ensures that human health and the environment is sufficiently protected. Consider the circumstance where PFOA is less than 0.014 micrograms per liter in a water body - such as 0.009 micrograms per liter. But a combination of other PFASs, such as PFOS, PFNA, adds up to a total concentration of 0.07 micrograms per liter. While the 0.009 micrograms per liter of PFOA may not cause serious harm to human health, the combination of many PFASs in a water body could cause serious health risks whether through fish consumption, through drinking water or another form of human exposure.

Furthermore, as outlined in the section above regarding the proposed Water Quality Criteria for PFOA, the EPA should place the burden of treatment upon the point sources, not the public water systems. Promulgating Water Quality Criteria accomplishes this goal.

Therefore, the OEC petitions the Administrator to take the necessary precautions to protect the public health from high concentrations of PFASs, setting the Water Quality Criteria at 0.07 micrograms per liter.

d. The OEC petitions the Administrator of the EPA to issue a Water Quality Standard for the Ohio River that protects the watershed from the dangers of PFOA and PFASs.

If the EPA promulgates the Water Quality Criteria established above, it must take immediate action to protect the water bodies most inundated by PFOA and other PFASs. While this petition focuses on the Ohio River, the OEC would be remiss not to mention that the EPA should consider taking immediate action to protect water bodies in other seriously affected regions, such as Minnesota, New York, Vermont, or New Jersey.

The EPA could take immediate action by issuing a national Water Quality Standard under its authority at 33 U.S.C. §1314(c)(4)(B). Additionally, the agency could coordinate with the OEPA, the Ohio River Valley Sanitation Commission ("ORSANCO"), and the several states of the Ohio River Valley to develop a Water Quality Standard that protects the River from PFOA and PFASs. When the EPA decides to develop these water quality standards, it should choose the method that will protect the River efficiently and expeditiously.

Ohio's government has recognized the risk PFOA poses to its citizens, as evidenced by its recent lawsuit against DuPont.[210] The federal EPA could coordinate with the Ohio EPA to develop Water Quality Standards quickly and efficiently and in line with the Water Quality Criteria proposed above. Alternatively, the EPA could coordinate with ORSANCO, though recently that commission proposed eliminating its Pollution Control Standards for the River.[211] Whatever avenue the EPA decides to take, it must act quickly to ensure that companies are not dumping tons of unregulated PFASs into the Ohio River, even if PFOA emissions have reduced drastically in the region since the scandal of the Washington Works plant.

V. The EPA should regulate PFOA and other PFASs under the SDWA.

Unlike the CWA, the SDWA does not contain a clear statement of U.S. purpose or national policy with regards to the regulation of public water systems. However, the primary tools of the SDWA, its "Primary Drinking Water Regulations," have a very specific definition pertinent to this Petition for Rulemaking. The SDWA defines a "Primary Drinking Water Regulation" as a rule that governs public water systems, "specifies contaminants which, in the judgment of the Administrator, *may have any adverse effect* on the health of persons," specifies a maximum contaminant level or a treatment technique if maximum contaminant level determinations are not economically or technologically feasible, and contains "criteria and procedures to assure a supply of drinking water which dependably complies with such maximum contaminant levels."[212]

Thus, the OEC submits this Petition for Rulemaking because the EPA must establish drinking water regulations that account for all contaminants that may have an adverse effect on public health. In addition, this Petition hopes to provide scientifically verifiable means through which the EPA can assist public water systems in effectively protect public health. In this case, the OEC believes that PFOA and PFASs satisfy the requirements of the SDWA, as provided in detail in this Petition for Rulemaking.

a. The Administrator of the EPA has the authority to establish a Primary Drinking Water Regulation under the SDWA.

Between 2013 and 2015, public water systems across the country monitored 30 contaminants as required by the third "Unregulated Contaminant Monitoring Rule," ("UCMR") a process put in place by the 1996 amendments to the SDWA.[213] During this period, not only did the EPA

---

[210] See Supra FN 163.

[211] The Ohio Environmental Council and other public interest environmental groups submitted comments in opposition to the elimination of the pollution control standards specifically because it would eliminate a coordinated method through which the several States of the Ohio River could protect against pollutants like PFOA or other PFASs. For more information on the repeal of ORSANCO's Pollution Control Standards, see *Pollution Control Standards*, OHIO RIVER VALLEY SANITATION COMMISSION, http://www.orsanco.org/programs/pollution-control-standards/.

[212] 42 U.S.C. §300f(1)(A) - (D), emphasis added.

[213] *Third Unregulated Contaminant Monitoring Rule*, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, (December 9, 2016), https://www.epa.gov/dwucmr/third-unregulated-contaminant-monitoring-rule. See also 42 U.S.C. §300g-1(b)(B)(ii).

mandate public water systems to monitor for PFOA, the EPA considered five other PFASs: PFOS, PFNA, perfluorohexane-sulfonic acid ("PFHxS"), perfluoroheptanoic acid ("PFHpA"), and perflurobutanesulfonic acid ("PFBS").[214]

Following the administration of this monitoring program, the EPA issued the aforementioned Drinking Water Health Advisory, instead of choosing to regulate the contaminant directly by issuing a Primary Drinking Water Regulation. While the OEC disputes that decision of the agency, the fact that it chose to issue an Advisory, or even consider PFOA, PFOS, and other similar compounds under the UCMR program, demonstrates that the agency has the authority to regulate this group of compounds under the SDWA. Thus, the agency could - indeed, should - regulate PFOA either through the emergency powers conferred upon the EPA Administrator under the SDWA, or through the ordinary procedure for developing a national "Primary Drinking Water Regulation" under the same Act.

i. The Administrator can regulate perfluorooctanoic acid under the emergency powers of the SDWA.

First and foremost, the Administrator of the EPA has the authority to use emergency powers to protect the health of persons from contaminants[215] in drinking water sources. Specifically, when the Administrator receives information regarding the presence of a contaminant in a public water system or other source of drinking water, the administrator may take necessary actions if the contaminant presents "an imminent and substantial endangerment to the health of persons, and...appropriate State and local authorities have not acted to protect the health of such persons."[216] These emergency powers present a broad and extensive range of tools to protect public health, including requiring alternative water supplies (provided by those who caused the public endangerment) and civil actions against perpetrators.[217] This is a non-exhaustive list of powers - in the end, the Administrator may take "such actions as he may deem necessary in order to protect the health of such persons."[218]

Therefore, if the evidence shows that a public water system is sufficiently inundated with a contaminant, even if that contaminant is not regulated by the EPA, the Administrator can take actions to protect the public when that contaminant poses a substantial endangerment to the health of persons.

Thus, even if the EPA erroneously determines that PFOA does not deserve a national Primary Drinking Water Regulation, the Administrator should use his emergency powers to protect the public in regions where abnormally high levels of PFOA have been detected. As outlined in §2, different places across the nation have experienced PFOA and PFAS concentrations well above the current Health Advisory or any reasonably safe levels. These communities deserve assistance

---

[214] Id.

[215] In the context of the Safe Drinking Water Act, "contaminant" means "any physical, chemical, biological, or radiological substance or matter in water." It does not refer only to contaminants actually regulated under the Safe Drinking Water Act. 42 U.S.C. §300f. (6).

[216] 42 U.S.C. §300i. (a).

[217] Id.

[218] Id.

when dealing with pollution that exists in their public water systems due to the fault of others who decided they would not take the necessary precautions. The EPA should provide that assistance and assist local communities as they take action against the people who caused the pollution in the first place.

ii. If the Administrator has sufficient information on PFOA and PFASs, he can use it to promulgate a Primary Drinking Water Regulation under the SDWA.

However, even if the Administrator were to determine that he should not use his emergency powers in the context of PFOA, the EPA must still administer a Primary Drinking Water Regulation under the SDWA. The EPA receives its authority to regulate contaminants through drinking water regulations under 42 U.S.C. §300g-1(b)(1)(A)(i)-(iii). In addition, the EPA can promulgate interim national Primary Drinking Water Regulations, as provided for under 42 U.S.C. §300g-1(b)(D).

Generally, the Administrator promulgates a national Primary Drinking Water Regulation when he or she makes the following three determinations:

(1) "the contaminant may have an adverse effect on the health of persons;
(2) the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and
(3) in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems."[219]

Upon making these determinations and the publishing of a national Primary Drinking Water Regulation, the Administrator must also publish a cost benefit analysis, specifically explaining "whether the benefits of the maximum contaminant level justify, or do not justify, the costs" as determined through the analyses required under 42 U.S.C. §300g-1(b)(3)(C).[220]

b. The OEC proposes the following Primary Drinking Water Regulation that would regulate PFOA at 0.014 micrograms per liter and PFASs at 0.07 micrograms per liter.

Using its authority under 42 U.S.C. §300g-1(b)(1)(A)(i)-(iii), the EPA must promulgate a Primary Drinking Water Regulation that matches the Maximum Contaminant Level recently established by the New Jersey Department of Environmental Protection: 0.014 micrograms per liter for PFOA. Additionally, the EPA should promulgate a Primary Drinking Water Regulation that limits PFASs as a family of substances to 0.07 micrograms per liter. For a clear statement of the proposed regulations, see Attachment 1.

While the OEC understands that the EPA recently issued a Health Advisory covering PFOA and PFOS and may still be internally considering a Primary Drinking Water Regulation that would regulate these two PFASs, the OEC believes the time for inaction and comprehensive scientific investigation has passed. The agency must act now, rather than push the decision further and

[219] 42 U.S.C. §300g-1(b)(1)(A)(i)-(iii).
[220] 42 U.S.C. §300g-1(b)(4)(C).

further into the future. The science shows the danger of PFOA, and the lack of science regarding all PFASs mandates caution. Thus, the OEC will show how PFOA and PFASs satisfy the three prong test required under the SDWA.

i. PFOA and PFASs may have an adverse effect on the health of people.

Section II of this Petition establishes the health risks of PFOA and PFASs. PFOA in particular is linked with the following health conditions:

(1) high cholesterol
(2) ulcerative colitis
(3) thyroid disease
(4) testicular and kidney cancer
(5) pregnancy-induced hypertension

PFASs pose a risk due to the lack of sufficient knowledge regarding their potential health risks. While a massive body of knowledge has been compiled regarding PFOA through the efforts of many researchers and the C8 Science Panel, many PFASs have been subject to little to no toxicology research. Thus, even while the EPA does not know all of the health effects of PFASs, it continues to allow polluters to discharge them into the waters of the United States. If the EPA fails to promulgate a Primary Drinking Water Regulation that also covers PFASs, it may allow a toxic mixture to form in public water supplies before we adequately understand the effects of the thousands of PFASs that exist. The EPA must follow the Precautionary Principle and protect the public now, rather than later.

Thus, because PFOA and PFASs may have an adverse effect on the health of people, the proposed Primary Drinking Water Regulation satisfies the first prong of the test.

ii. PFOA and PFASs are known to occur and have a high chance to occur in many public water systems.

The EPA's own Health Advisory outlines the data regarding the inundation of PFOA and other long-chain PFASs throughout the water systems that serve millions of Americans. Approximately 2% of U.S. public water systems detected PFOA at greater than 0.02 micrograms per liter; however, the monitoring for PFOA did not account for updated science used by New Jersey to calculate its Maximum Contaminant Level of 0.014 micrograms per liter.[221] And as noted in §2, nearly one third of all public water systems were not evaluated during the third administration of the Unregulated Contaminant Monitoring Rule. Many of those unmonitored water systems are private groundwater wells that may not have access to funds to install the necessary treatment technology for PFASs. If at least 2% of U.S. public water systems detected PFOA at greater than 0.02 micrograms per liter, then presumably many systems have PFOA levels greater than 0.014 micrograms per liter, or close to that level.

Opponents may argue that 2% of public water systems is not "many public water systems." However, notwithstanding the unknown number of systems with more than 0.014 micrograms

[221] See Supra FN 19; see also Supra FN 153.

per liter, "2%" is still a large number of public water systems in a country with over 300 million citizens. "Many" does not mean "majority" of public water systems. Hundreds if not thousands of public water systems have high concentrations of PFOA and other PFASs, even if those concentrations do not currently exceed the present 0.07 micrograms per liter of the EPA's nonbinding Health Advisory. The EPA cannot ignore this reality.

While less data exists regarding the inundation of PFASs in public water systems, the EPA does have data on PFOA, PFOS, PFNA, PFHxS, PFHpA, and PFBS. However, during the UCMR systems were not required to report unless they detected concentrations above 0.02 micrograms per liter. If the EPA chooses not to regulate PFOA of PFASs, it should, at the very least, conduct additional studies to detect the concentrations of all PFASs that persist in U.S. public water systems.

Thus, the data establishes that at least 2% of public water systems are inundated by PFOA at a concentration higher than the 0.014 micrograms per liter referenced in our proposed Primary Drinking Water Regulation. If the EPA considers the lack of data from thousands of other public water systems, along with the likely case that many public water systems had concentrations between 0.01 micrograms per liter and 0.02 micrograms per liter of PFOA, then PFOA and PFASs satisfy the second prong of the statutory test: PFOA and PFASs have a high chance to occur in many public water systems.

iii. The regulation of PFOA and PFASs presents a meaningful opportunity to reduce health risks for people served by public water systems.

The EPA has the authority to regulate PFOA and PFASs. We know that PFASs harm the public in many serious ways, whether through increased cancer risks or other toxicological effects. But more importantly, the regulation of PFOA and PFASs presents a meaningful opportunity to reduce the health risks for people served by public water systems. The EPA must ensure that other PFASs never pose a risk to communities like PFOA posed a risk to the people that lived along the Ohio River for decades.

The EPA might claim that it does not need to regulate PFOA directly because of its PFOA Stewardship Program or its Health Advisory. It might claim that it does not need to regulate PFASs because the science has not settled regarding their cumulative danger. Right now, if a company decided to begin using PFOA again in the future, no regulations actually stop that company from doing so. Every week, new stories arise where yet another community detects significant levels of PFOA because a local fire department uses certain types of firefighting foam. For instance, early in March 2018 eight private drinking wells in Doylestown Township, Pennsylvania had concentrations of PFOS and PFOA over 0.07 micrograms per liter.[222]

Shorter chain PFASs most likely will have similar toxicological effects as PFOA, once scientists do their due diligence. If the EPA does not act, then local citizens will resort to massive class action lawsuits like the suits filed against DuPont, Chemours, and 3M. Or, state Attorneys

[222] Chris Ullery, *Eight private wells in Doylestown, Cross Keys above EPA PFAS limits*, THE INTELLIGENCE, (March 7, 2018), http://www.theintell.com/news/20180307/eight-private-wells-in-doylestown-cross-keys-above-epa-pfas-limits.

General will file a multiplicity of nuisance claims for each and every PFAS as their health risks are uncovered by scientists. To think that PFOA is the only dangerous substance out of thousands of PFASs to pose a risk to human health and the environment is an arrogant conclusion at best. When a pharmaceutical company produces new drugs for human consumption, that drug must undergo extensive testing through the FDA before they can enter the market. Industrial companies should not discharge unregulated PFASs into the country's waterways before we properly understand their toxicological effects.

When combined with the proposed Water Quality Criteria and Water Quality Standards discussed in §4, and the TSCA initiatives discussed in §6, the EPA has the opportunity to create a holistic framework for managing these substances from production to emission to consumption. Under TSCA, the EPA can either ban PFASs outright or order substantial toxicological testing. If a PFAS is approved for use even if it has health effects at certain levels, the SDWA and CWA regulations will ensure that companies cannot emit these substances into our waterways in large quantities.

Furthermore, the CWA and SDWA regulations work together to ensure that both point sources and public water systems take action to protect against PFOA and PFASs. If a water body has over 0.014 micrograms per liter of PFOA or 0.07 micrograms per liter of all PFASs, the state would issue a TMDL. Through permits, point sources would have limitations placed upon their discharges of PFASs.

Similarly, if a public water system intakes water with a concentration of 0.014 micrograms per liter for PFOA or 0.07 micrograms per liter for PFASs, it would need to take corrective action and install technology such as granulated activated carbon filtration or reverse osmosis. But in theory, if a state acts to protect the water body from point sources, then public water systems should never intake concentrations of PFOA or other PFASs above the proposed Primary Drinking Water Regulation.

The EPA has an opportunity to protect human health and the environment from PFASs. The European Union has already started to act. New Jersey has started to act. The United States can also lead the way and protect the consumers of public water systems from the health risks of PFOA and PFASs.

VI. The EPA should issue a rule prohibiting the manufacturing, processing, and distribution of PFOA and require a manufacturer's testing order for other PFASs under TSCA.

In the mid-1970s, Congress found that "human beings and the environment are being exposed each year to a large number of chemical substances and mixtures" and that "there are some whose manufacture, processing, distribution in commerce, use, or disposal may present an unreasonable risk of injury to health or the environment."[223] In response, Congress enacted TSCA, empowering EPA with the authority to require reporting, record-keeping and testing requirements, and restrictions relating to chemical substances or mixtures. Forty years later,

[223] 15 U.S.C.A. § 2601(a) - (b).

Congress amended TSCA through the Frank R. Lautenberg Chemical Safety for the 21st Century Act, increasing the law's requirements for evaluation and transparency. As President Obama emphasized during the signing of the landmark reforms to TSCA, the amendments "do away with an outdated bureaucratic formula to evaluate safety, and instead focus solely on the risks to our health."[224]

In enacting TSCA, Congress directed EPA to regulate all chemical substances that present or will present unreasonable risks of injury to health or the environment. The Act therefore was and still is designed to protect against dangers from the manufacturing and distribution of chemicals, that if unregulated can cause irreparable injury. Risks to human health and the environment from PFOA and PFASs, as we have outlined so far, are the exact sort of risks TSCA was designed to prevent. The many avenues of exposure to PFOA's health effects - through air, water, and soil - make the risks of PFOA practically inescapable. Each day we fail to regulate PFOA, we fail to prevent deaths and illnesses that have devastated communities across the country. We continue to allow situations where manufacturers must pay millions in legal bills to compensate victims of PFOA exposure. By even the most conservative definition, PFOA and PFASs create the unreasonable risks TSCA was designed to prevent.

a. The Administrator of the EPA has the authority to prohibit the manufacturing, processing, and distribution of PFOA and other PFASs, and should grant the relief requested under Section 6 of TSCA.

To facilitate TSCA's Congressional intent, the EPA Administrator holds the authority to prohibit a chemical substance with serious health and environmental impacts like PFOA. Under TSCA section 6(a), the EPA must first determine "that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture . . . presents an unreasonable risk."[225] In particular, the EPA must conduct this evaluation "without consideration of costs or other non-risk factors identified as relevant to the risk evaluation by the Administrator, under the conditions of use."[226]

Furthermore, in deciding whether to ban or phase out a use of a chemical, the Administrator may consider "whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute."[227] Required considerations do not override the requirement for restrictions to the extent necessary so that the substance no longer presents an unreasonable risk, without consideration of costs and other non-risk factors.[228]

Under this administrative process, the EPA has the full authority under TSCA to issue a rule prohibiting the manufacture, processing, and distribution in commerce of PFOA and other PFASs. EPA's recognition of its authority over PFOAs, in fact, dates back to the inception of

---

[224] Remarks by the President at Bill Signing of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, June 22, 2016.
[225] 15 U.S.C. § 2605(a).
[226] Id.
[227] 15 U.S.C § 2605 (c)(2)(C).
[228] 15 U.S.C. § 2605(a).

EPA's 2006 PFOA Stewardship Program. According to the Agency, EPA launched the PFOA Stewardship Program due to concerns about the impact of PFOA and long-chain PFASs on human health and the environment, including their persistence, presence in the environment and in the blood of the general U.S. population, long half-life in people, and developmental and other adverse effects in laboratory animals.

Studies, as described in Section II, show that any use of PFOA poses an unreasonable risk to human health and safety.[229] The goal of the stewardship program was to have the participating manufacturers commit to reducing PFOA from facility emissions and product content by 95 percent no later than 2010, and to work toward eliminating PFOA from emissions and product content no later than 2015.[230] While voluntary efforts are laudable, they do not ensure a reduction of unreasonable risks to human health and the environment.

The EPA and PFOA manufacturers have curbed PFOA use, but based on the unreasonably high threat to humans and the environment of its continued manufacturing, processing and distribution, we need EPA *regulatory* action. Even with the reductions of the Stewardship Program, Section II of this Petition shows that PFOA continues to inundate public water systems across the country. Furthermore, and due in part to the efforts to curb the use of PFOA, many alternatives have emerged and are already used in commerce. Thus, the EPA must use its authority under section 6 of TSCA to eliminate the manufacturing of PFOA in light of known health impacts and known alternatives for the substance.

Under TSCA § 21 "any person may petition the Administrator to initiate a proceeding for the issuance, amendment, or repeal of a rule" under enumerated sections of title 15 of the United States Code. To take action on its own, EPA would need to make a determination of whether a chemical substance or substances present an unreasonable risk to human health or the environment - otherwise referred to as a risk assessment under TSCA §6. As petitioners, the OEC must submit a basis for action based on scientific evidence that is *reasonably comparable* in its quality and scope to a risk evaluation under §6. The action proposed by the OEC must reduce the risks of the chemical substance so that the chemical substance or mixture no longer presents unreasonable risks under all conditions of use. According to its own statements, EPA interprets TSCA §21 as requiring the petition to present a scientific basis for action that is reasonably comparable, in its quality and scope, to a risk evaluation under TSCA §6(b).

Based on the documented health effects presented in the EPA's Health Advisory and C8 Scientific Panel reports, supplemented by the additional reported environmental and health effects outlined in this Petition, the following sections provide information in accordance with the promulgated risk evaluation regulations. The OEC therefore has demonstrated through this petition a basis for action based on scientific evidence that is *reasonably comparable* in its quality and scope to a risk evaluation under §6. The facts show that the Administrator must determine that the risks are so unreasonable as to require banning PFOA.

---

[229] *2010/2015 PFOA Stewardship Program Factsheet,* UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/fact-sheet-20102015-pfoa-stewardship-program#launch.

[230] Id.

i. The manufacture, processing, distribution in commerce, use, and disposal of PFOA and other PFASs presents an unreasonable risk to human health.

In June of 2017, EPA regulations were promulgated to develop a process for a risk evaluation under TSCA §6.[231] As part of this process, EPA must evaluate both hazard and exposure, exclude consideration of costs or other non-risk factors, and use the best available science to ensure the EPA bases its decisions on credible information.

Hazard Assessment

A Hazard Assessment includes identifying the types of hazards to health or the environment posed by a chemical substance.[232] For all intents and purposes, the EPA has conducted its requisite Hazard Assessment for PFOA. The Court-ordered C8 Science Panel found probable causation between PFOA exposure and the following health effects: high cholesterol, thyroid disease, pregnancy-induced hypertension, ulcerative colitis, and kidney/testicular cancer. Tissue accumulation of PFOA was also prominently evident in testes, uterus, kidneys, lungs, heart, and muscle.[233] Immune system function in studies performed on children and adults displayed decreased vaccine response, suggesting delayed or decreased immune system function.[234] When the EPA issued its Drinking Water Health Advisory for PFOA, it agreed with the analysis of the C8 Science Panel, concluding that "the weight of evidence for human studies supports the conclusion that PFOA exposure is a human health hazard." [235]

This analysis of the hazards conducted by the C8 Science Panel has been supplemented by the over 4,000 peer-reviewed studies on the detrimental health effects of PFOA conducted in the U.S. and abroad over the past five years.[236]

Exposure Assessment

Similarly, the EPA has also already conducted the requisite Exposure Assessment as demonstrated in the EPA's own reports. In the EPA's May 2016 PFOA Health Advisory Report, the panel of experts determined that 80% of their recommended 0.07 µg/L lifetime PFOA limit is sourced from "dust, diet, and air."[237] The major venues of PFOA exposure, as defined by the EPA, are thus: drinking water, food, air, soil, biosolids, and consumer products.[238]

We addressed PFOA drinking water exposure above in Section II, including risks to public water systems due to the high concentrations of the substance identified across the country.[239] We will take the opportunity here to outline the findings as they relate to other exposure routes as it pertains to our discussion under TSCA. First, ingestion of PFOA from food is a significant exposure source for both adults and children. Due to its ability to be deposited into soils, PFOA

---

[231] See 40 CFR §702.41.
[232] 40 CFR §702.41(D).
[233] Supra FN 129.
[234] Supra FN 19.
[235] Supra FN 77.
[236] Supra FN 26.
[237] Supra FN 19, at 10.
[238] Id.
[239] Supra Section II, b, ii.

can be taken up by plants, particularly shoot or root crops, allowing for contamination of feed or grasses fed to cattle and other livestock. Cattle fed PFOA contaminated feed were found to have accumulation in liver, muscle, and milk. Bioaccumulation of PFOA also occurs in fish, most prevalently in Great Lakes "wild" fish, and cannot be reduced by cooking. Until January of 2016 when the U.S. Food and Drug Administration amended food additive regulations, PFOA was also used in manufacturing of various types of food packing that repelled oil and water for paper and paperboard, including microwave popcorn bags, fast food wrappers, candy wrappers, and pizza box liners.[240] Contamination of prepared foods also occurs via nonstick-lined cookware when heated, although, the observed concentration is much lower than coated papers, and was greater in new pans rather than those that had previously been used.[241]

Another serious exposure risk occurs the heating of nonstick-lined cookware emits PFOA into indoor air. Researchers find PFOA in the air of indoor offices as well as stores selling outdoor equipment, furniture and carpeting, as shown in blood serum testing samples. In tandem, because of its' prominent use in textiles, PFOA is prevalent in inhalable dusts in indoor settings, including homes and offices. Inhalation of indoor dusts is another primary route of PFOA exposure for two-year-old children, especially, in highly exposed cases, dwarfing contamination by food.[242]

Populations living and working in or near manufacturing sites also experience significant exposure to PFOA. The C8 Science Panel makes clear that PFOA contamination persists heavily in soils near manufacturing and disposal sites, as well as military bases that employ the use of firefighting foams containing PFOA; concentrations increase as soil depth increases, providing the evidence of groundwater contamination from migration.[243] Unintentional inhalation of contaminated soils is yet another potential route for exposure, particularly for those working in or around locations that manufacture or dispose PFOA. PFOA-containing biosolids also play a role in contaminating surface waters near where such biosolids are applied.

The OEC has summarized the activities of the C8 Science Panel, the EPA's PFOA Health Advisory, volumes of other peer-reviewed research, and numerous public and private sector reports. Taken together, this data is comparable to the process dictated by section 6 regulations. Utilizing these assessments, the Administrator must make a determination based on the weight-of-scientific-evidence that PFOA poses an unreasonable risk to the health and environment. The science requires this and no other conclusion.

ii. Technically and economically feasible alternatives that benefit health or the environment, compared to the use of PFOA, are reasonably available as a substitute.

When deciding to prohibit or restrict a specific chemical substance, the Administrator considers technically and economically feasible alternatives.[244] In evaluating such alternatives, the

[240] Supra FN 19, at 21.
[241] Id.
[242] Id. at 22.
[243] Id. at 22.
[244] 15 U.S.C.A. 2605(c)(2)(C).

Administrator compares the risk of those alternatives harming the environment and considers whether those substances are readily available as substitutes.[245]

After the inception of the 2006 PFOA Stewardship Program, the phase out of PFOA led to an insurgence of the production of alternatives to replace PFOA. Due to the fact that full chemical identities and the volume of the chemicals manufactured as replacements are considered Confidential Business Information (CBI) and prohibited from disclosure under TSCA, the few alternatives that are public information are known primarily by their industry names. In this instance, of the eight companies that participated in the Stewardship Program, there are seven known alternatives and one postulated alternative. But largely, the chemical structures are considered proprietary information for each respective corporation. Each alternative contains shorter chain carbon chemistries that, with cooperation with the desires of the EPA via the Program, are intended to be less persistent in the environment as well as nontoxic to humans. The currently identified alternatives are:

(1) ADONA, an emulsifier created by 3M for its subsidiary Dyneon, and a C6 perfluoropolyether;[246]

(2) PFBS, or perfluorobutane sulfonate, a C4 fluorocarbon PFOA replacement manufactured by 3M;[247]

(3) GenX, DuPont's alternative to PFOA, and a C6 PFPE;[248]

(4) Solvera and Fluorolink, - Solvera is a C5 fluorocarbon while Fluorolink is a C6 fluorocarbon;[249] AG-E600 AsahiGuard, created by the Asahi Glass Company;

(5) PFHxA (perfluorohexanoic acid), used by Daikin;[250]

(6) Cartaguard® KHI, Clariant's alternative and a C3 fluorocarbon;[251] and

(7) Arkema's Kynar 500® PVDF and BASF's Styronal® ND 430.[252]

While the most recent studies currently available on these PFOA alternatives (see the footnotes for each alternative) show risks to human health, the alternatives *potentially* pose less risk than that of their long-chain predecessor. Furthermore, the widespread use of these alternatives supports the implication that these alternatives are economically feasible. While we urge the

---

[245] Id.

[246] Information on the chemical structure of this PFOA alternative can be found in the research of Zhanyun Wang, Ian T. Cousins, Martin Scheringer, Konrad Hungerbühler. *Fluorinated alternatives to long-chain perfluoroalkyl carboxylic acids (PFCAs), perfluoroalkane sulfonic acids (PFSAs) and their potential precursors,* Environment International 60 (2013) pp. 242–248, http://www.greensciencepolicy.org/wp-content/uploads/2014/10/Wang-et-al.-2013.pdf

[247] Id.

[248] Id.

[249] Id.

[250] Id.

[251] Id.

[252] Detailed information about Arkema's Kynar 500® PVDF and BASF's Styronal® ND 430 have not been released.

EPA to order further testing of these alternatives via Testing Order under TSCA §4, a consideration of these alternatives, and the fact that most are currently in production, bolsters the OEC's argument that a total §6 prohibition is warranted with regards to PFOA.

iii. The OEC proposes the following requirement to apply to PFOA to the extent necessary so that it no longer presents an unreasonable human health risk.

Thus, after publicly and privately funded research, voluntary actions, class action and state attorneys general lawsuits, countless otherwise avoidable medical conditions and emergencies, and continued threats to humans and the environment, the EPA must take definitive action to ensure that PFOA no longer presents an unreasonable human health risk. It is thus beyond comprehension that the EPA has not yet made a full regulatory unreasonable risk determination based on not only the definitive information of the risks readily available to EPA, but information compiled and published by the EPA. The only reasonable regulatory action available to EPA is to issue a regulation prohibiting the manufacturing, processing, or distribution in commerce of PFOA. For a clear statement of this prohibition, see Attachment 1.

b. The EPA should order a Section 4 Test Order for PFASs under TSCA.

As outlined above, PFASs, including the alternatives to PFOA, may themselves cause an unreasonable risk to human health and the environment. While data is not sufficiently available for the Administrator to determine that regulation under TSCA §6 is warranted for some or all of these substances, there is little doubt that existing information about the risks posed by PFASs satisfy the criteria for a Testing Order under TSCA §4.

When Congress enacted TSCA, it mandated that "it is the policy of the United States that adequate data be developed with respect to the effect of chemical substances and mixtures on health and the environment."[253] Congress further put the onus and responsibility for developing such data on "those who manufacture and those who process such chemical substances and mixtures."[254] To fulfill that policy, Congress created within TSCA a requirement for the Administrator of EPA to direct testing on a chemical substance or mixture that "may present an unreasonable risk of injury to health or the environment."[255] Specifically, the EPA is required to direct a testing order if it finds the following criteria met:

(1) the "manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,"

(2) "there is insufficient information and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted," and

---

[253] 15 U.S.C. §2601(b)(1).
[254] Id.
[255] 15 U.S.C. §2603(a).

(3) "testing of such substance or mixture with respect to such effects is necessary to develop such information."[256]

i. PFASs may present an unreasonable risk to human health and the environment.

The first criteria that must be met to commence a §4 testing order is a determination that the "manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, *may present* an *unreasonable* risk of injury to health or the environment." As emphasized above, the operative terms in this criterion are that the substance "may present" a risk and that the risk must be "unreasonable."

The "may present" finding has been determined by EPA, and supported by Circuit Court opinions, as the existence of an unreasonable risk of injury that is more than merely theoretical, speculative, or conjectural.[257] The Courts have interpreted TSCA as empowering EPA to issue a test order on health grounds where it finds "more-than-theoretical basis for suspecting that the chemical substance in question presents an unreasonable risk of injury to health." Specifically, the Court in *Ausimont U.S.A., Inc.* determined that in regard to a §4 testing order, unreasonableness of "risk implicates two concepts - toxicity and exposure."[258]

This Petition has shown that PFASs pose more than a theoretical, speculative, or conjectural "unreasonable risk of injury." We have thoroughly outlined a number of studies that show the toxicity of PFASs, and *the Madrid Statement on Poly- and Perfluoroalkyl Substances* provided a hard look at that research. The Madrid Statement outlines the PFAS studies that show toxicity to livers, neonatal toxicity and death, and tumors in multiple organ systems, cancers, and decreased immune response.[259]

The routes of human and environmental exposure to PFASs, too, are varied, persistent, and have been firmly established. As demarcated in the Madrid Statement, we can find PFASs in indoor and outdoor environments, in wildlife and in humans, in tissue and bodily fluids, and all over the globe. Exposure occurs for workers via emissions from industrial processes and for public servants in military and firefighting operations. Most ubiquitously, however is exposure to everyday American families through consumer products into air, household dust, food and drinking water.[260]

These findings surrounding the toxicity and exposure to varying populations through varying pathways more than satisfies the criteria for a TSCA §4 testing order that PFASs "may present an unreasonable risk of injury to health or the environment."[261]

---

[256] Id.
[257] *Chem. Mfrs. Ass'n v. EPA,* 859 F.2d 977, 983-985 (D.C. Cir. 1988).
[258] 838 F.2d at 96.
[259] Supra FN 165.
[260] Id.
[261] 15 U.S.C. §2603(a)(1).

ii. There is insufficient information to determine or predict the effects of PFASs, and testing is necessary to develop this information.

Although some scientific evidence on the potential risks of PFASs exists, there is much that remains unknown. As we point out above, "little to no information [exists in the public domain] about their fate/transport, exposure, and toxicological effects...or even awareness to study them...although existing evidence suggests a need for concern."[262] The information gathered so far on PFASs that could serve as alternatives to PFOA supports the non-speculative existence of an unreasonable risk of injury. For example:

(1) In mammalian toxicology studies sponsored by 3M, ADONA™ was found to be "moderately toxic" orally, and "practically non-toxic" dermally, in acute rat studies as well as a mild skin irritant and moderate-to-severe eye irritant in rabbits. Performed Ames tests showed that ADONA™ was not a bacterial mutagen, and mammalian internal health studies on rats proved it was non-clastogenic.[263] ADONA™, however, had decreased effects on body weights and food consumption and increased effects on liver/kidney weights in males as well as increased adrenal weights in females. Liver weight significantly increased in males at doses of 30 and 100 mg/kg/day, and no significant increase in liver weight was seen in females. No-observed-adverse-effect-levels (NOAELs) for males and females were 10 mg/kg/day and 100 mg/kg/day, respectively. Based on the NOAELs for both sexes, ADONA™ toxicity was deemed acceptable for its intended use as a PFOA replacement.[264]

(2) In an independent study of PFBS, the Minnesota Department of Health observed subchronic/chronic noncancer health risks in rats, including: decreased hemoglobin, decreased red blood cell count, increased liver size including evident hyper-increase of hepatic cells in the liver, and secondary observations of neurotoxicity with inconclusive effects. Clastogenic effects were not derived because PFBS had not been classified in regard to its potential carcinogenicity.[265]

(3) An independent study undertaken by researchers from the Institute of Chemical and Bioengineering in Zurich, Switzerland, and the Department of Applied Environmental Science at Stockholm University, evaluated the various replacements announced by the above manufacturers in terms of their persistence in the environment. The researchers postulated the identity of Daikin's alternative as PFHxA, as it was not publicly released, and concluded that PFPE-based alternatives, namely ADONA™ and GenX, are persistent in the environment, though ADONA™ does begin to degrade to volatile substances at 125 °C. Via their findings, they postulated that PFPEs degrade slowly in air and have lifetimes of greater than 46 years. Information on other alternatives, though, is nominally scarce or incomplete.[266]

While initiated, the studies are far from complete, and the information on others is insufficient to adequately demonstrate a risk evaluation under §6. As mentioned above, Solvay's Solvera® has 5 carbon links, Fluorolink®, Asahi's EG-E600 AsahiGuard E-Series, Daikin's possible alternative have 6 carbon links, while Clariant's Cartaguard® KHI has only 3 carbon links.

---

[262] Supra at FN 26.

[263] SC Gordon, *Toxicological evaluation of ammonium 4,8-dioxa-3H-perfluorononanoate, a new emulsifier to replace ammonium perfluorooctanoate in fluoropolymer manufacturing*, Regul Toxicol Pharmacol.. 2011 Feb:59(1):64-80, available at: https://www.ncbi.nlm.nih.gov/pubmed/20875479.

[264] Id.

[265] *2011 Health Risk Limits for Ground Water*, MINNESOTA DEPARTMENT OF HEALTH, (2011), http://www.health.state .mn.us/divs/eh/risk/guidance/gw/pfbs.pdf.

[266] Supra FN 17.

Information about the carbon structures of Arkema's Kynar 500® PVDF and BASF's Styronal® ND 430 has not been publicly released. For the above corporations, human/animal and ecological toxicity reports have also not been publicly released, so health effects cannot be fully determined. Further, and as we referenced earlier, DuPont's GenX has only been considered in 26 peer-reviewed articles as of the publishing date of the referenced article.[267]

Furthermore, beginning in 2002, the agency issued a series of Significant New Use Regulations (SNURs) "affecting dozens of PFASs."[268] Through these TSCA §5 SNUR activities, the EPA has required companies to report to EPA their intent to manufacture (including import) these PFASs. However, The SNURs are initiated on the chemical's new use, and not the impact on human health through avenues of exposure. TSCA §4 testing orders though can focus the testing on the pathways to the most significant human health risk - in the case of PFASs, those paths are through sources of drinking water.

As we learn the seriousness of risk from the various PFASs and the extent of exposure increases, the need for testing, we believe, will transition into the necessity of regulatory safeguards. Yet testing must occur to develop the basis necessary for mitigating the risk of PFASs. The aforementioned Madrid Statement found that as "fluorinated alternatives are being marketed, little information is publicly available on their chemical structures, properties, uses, and toxicological profiles,"[269] and the Statement suggests that gaps exist in total available data on PSAS, specifically from the manufacturers. As the Statement concludes, "initial efforts to estimate overall emissions of PFASs into the environment have been limited due to uncertainties related to product formulations, quantities of production, production locations, efficiency of emission controls, and long-term trends in production history."[270] Furthermore, the efforts of the industry to move from PFOA to shorter chain alternatives over the past decade, although important in curbing PFOA's impact, has hastened the need for such testing of PFASs.

iii. The OEC proposes the following requirement to apply to PFASs that present an unreasonable human health and environmental risk.

As it pertains to PFASs, the three criteria for a TSCA §4 testing order are satisfied. Accordingly, we urge the EPA to require that testing on all PFASs to develop information with respect to the health and environmental effects for which there is an insufficiency of information. Using information garnered from those tests, the EPA can move closer to a determination regarding whether PFASs do or do not pose an unreasonable risk of injury to health or the environment.[271]

In §2 of this Petition we have outlined the health and exposure threats from PFOA and PFASs that require increased action by the EPA to regulate Americans' exposure. The established health risks of PFOA, which include high cholesterol, ulcerative colitis; thyroid disease; testicular and

---

[267] Id. at 2510.

[268] United States Environmental Protection Agency, *Risk Management for Per- and Polyfluoroalkyl Substances (PFASs) under TSCA,* https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-and-polyfluoroalkyl-substances-pfass

[269] Supra FN 165.

[270] Id.

[271] 15 U.S.C. §2603(a).

kidney cancer; and pregnancy-induced hypertension, are potentially the same in PFOA's short-chain alternatives. Also, like PFOA, the most significant exposure risk, however, is from ingestion of PFASs from contaminated drinking water. Furthermore, while a significant body of knowledge has been compiled regarding PFOA through the efforts of many researchers and the C8 Science Panel, many PFASs have little to know toxicology research (especially in regard to drinking water exposure).

As the EPA learns more and more about each PFAS, the EPA must also consider the potential risks of mixture toxicity. While the individual concentrations of one substance may not present a danger, the combined concentrations of all PFASs may pose an even greater risk than PFOA. The EPA must initiate these studies to gain the requisite knowledge to understand the potential risks of mixture toxicity caused by PFASs.

Therefore, the EPA may direct a §4 testing order for PFASs to all persons who manufacture or intend to manufacture[272] or process or intend to process[273] PFASs. At a minimum, EPA should direct this order to the manufacturers and processors who have used or plan to use PFASs as alternatives to PFOA. Furthermore, the OEC urges the EPA to promulgate a testing order on PFASs that focuses on drinking water related paths of exposure. Testing of drinking water exposure should support the development of drinking water related knowledge and literature and should focus, initially, on all of the following factors:

(1) waters in the vicinity of manufacturing and processing facilities known as point source discharges of PFASs to the environment;

(2) facilities PFAS have been used (such as textile or carpet manufacturers) and may have resulted in contamination to soil and groundwater; and

(3) landfills where leaching of PFAS from disposal of products that contain it has resulted in, or may have a significant risk of, contamination to soil and groundwater.

VII. The OEC asks the EPA to act on this Petition for Rulemaking and to respond within a reasonable timeframe.

Because PFOA and PFASs pose present and future threats to human health and the environment, the EPA and this nation must efficiently address the danger that these substances represent. The longer the EPA waits to act on this petition, the more U.S. citizens will experience irreparable harm from the dangers presented by PFOA and PFASs. More people will receive diagnoses for cancer and other serious illnesses, partially caused by exposure to PFOA and PFASs. The EPA must act now rather than sit on its hands and wait. And if the EPA decides to shirk this responsibility, it must provide a clear, responsive discussion of the science presented in this petition for rulemaking, especially the specific reasons why the agency believes PFOA and PFASs do not represent a danger to human health and the environment.

---

[272] The term "manufacture" under TSCA 15 U.S.C. §2602(9), means to import into the customs territory of the United States (as defined in general note 2 of the Harmonized Tariff Schedule of the United States), produce, or manufacture.

[273] The term "process" under TSCA 15 U.S.C. §2602(13), means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce.

In conclusion, the OEC reiterates its separate requests for prompt rulemaking under the CWA, the SDWA, and TSCA, respectively.

First, the OEC petitions the Administrator of the EPA to establish Water Quality Criteria for PFOA and PFASs under the CWA. Specifically, the OEC believes that the correct Water Quality Criteria for PFOA is 0.014 micrograms per liter. For PFASs, the OEC proposes 0.07 micrograms per liter.

Second, the OEC petitions the Administrator of the EPA to establish an emergency Water Quality Standard for the Ohio River that includes PFOA and PFASs. PFOA still poses a health risk to Ohioans, as evidenced by the Attorney General's decision to pursue legal action against two of the main polluters of PFOA and PFASs, DuPont and Chemours. This represents an instance where the Administrator of the EPA must exercise their authority to act outside the purview of the states to protect an important water body and the citizens who rely on that water body for their drinking water. Thus, the OEC petitions for the development of a Water Quality Standard for the Ohio River which includes the Water Quality Criteria for PFOA and PFASs proposed in this petition.

Third, the OEC petitions the Administrator of the EPA for the issuance of a National Public Drinking Water Regulation for PFOA and PFASs. The EPA's drinking water Health Advisory establishes the risk that PFOA poses to human health; additional scientific evidence further bolsters this argument for both PFOA and PFASs. Thus, the OEC proposes that the EPA regulate PFOA under the Safe Drinking Water Act at 0.014 micrograms per liter. Similarly, the OEC proposes that the EPA regulate PFASs under the Safe Drinking Water Act at 0.07 micrograms per liter.

Finally, pursuant to TSCA §21, the OEC petitions the Administrator of the EPA to ban the manufacturing, processing, and distribution in commerce of PFOA under TSCA §6, and to require comprehensive manufacturer testing be conducted on other PFASs under TSCA §4 for drinking water exposure.

Section 5 U.S.C. §555(e) of the APA requires prompt notice when an administrative agency denies a petition for rulemaking. This law embodies the procedural right to due process enshrined in the United States Constitution. In that spirit, the OEC asks that the EPA expeditiously consider this petition for rulemaking and approve, or deny, within a reasonable timeframe. And under TSCA §21(b)(3), the EPA must respond to the sections of our Petition promulgated under TSCA within 90 days.

We respectfully ask EPA to respond to this Petition by initiating rulemaking proceedings as requested in the petition no later than July 12, 2018, 90 days after this Petition should have arrived at the principal office of the Administrator of the EPA. The EPA should reply to all seven requests in this petition within the same timeframe, ensuring immediate protection of human health and the environment from the dangers of PFOA and PFASs.

Respectfully submitted,

Trent Dougherty
General Counsel
The Ohio Environmental Council
1145 Chesapeake Avenue, Suite I
Columbus, OH 43212
tdougherty@theoec.org
(614) 487-7506

Chris Tavenor
Law Fellow
The Ohio Environmental Council
1145 Chesapeake Avenue, Suite I
Columbus, OH 43212
ctavenor@theoec.org
(614) 487-7506

Attachment I

Water Quality Criteria for Human Health

Pollutant	CAS Number	Human Health for the consumption of Water + Organism (µg/L)	Human Health for the consumption of Organism Only (µg/L)	Publication Year	Notes
PFOA	335-67-1	0.014	0.014	20xx	*0.014 micrograms per liter is based on the MCL promulgated by the New Jersey Department of Environmental Protection.*
PFASs	xxxx[274]	0.07	0.07	20xx	*0.07 micrograms per liter is based on the original Health Advisory issued for PFOA and PFOS.*

[274] Because the OEC is requesting regulation of all PFASs, no single CAS number quantifies all PFASs together and many PFAS formulas are trade secrets. If the U.S. EPA would like the OEC to provide a list of the over 3000 PFASs on the market with publicly available CAS numbers, especially if that is the only way the agency will promulgate this regulation, the OEC will gladly provide that list.

Provisions for inclusion in a Water Quality Standard covering the Ohio River[275]

			Outside Mixing Zone Average	
Chemical	**Form**	**Units**	**Intakes**	**Outtakes**
PFOA	Total[276]	µg/L	0.014	0.014
PFASs	Total[277]	µg/L	0.07	0.07

Primary Drinking Water Regulation

Contaminant	**MCLG (µg/L)**	**MCL or TT (µg/L)**	**Potential Health Effects from Long-Term Exposure Above the MCL**	**Sources of Contaminant in Drinking Water**
PFOA	0.014	0.014	High cholesterol, ulcerative colitis, thyroid disease, testicular and kidney cancer, and pregnancy-induced hypertension	discharged from chemical factories; leachate at waste disposal sites; component of disposed firefighting foam
PFASs	0.07	0.07	See above; other potential health effects unquantifiable due to lack of testing. The uncertainty of the health effects of PFASs is a health risk itself.	See above

§6 TSCA Order

"PFOA" means perfluorooctanoic acid, identified as the substance with the CAS number 335-67-1 and chemical formula $C_8HF_{15}O_2$.

After December 31, 2018, no person may manufacture, process or distribute the substance PFOA in commerce.

---

[275] The following proposed text is based on the language of the Ohio river standards found at OAC 3745-1-32.

[276] This is a term of art used by the Ohio Environmental Protection Agency to describe the concentration of a substance in the Ohio River.

[277] or Total Mixture, since this is a combination of a lot of different chemicals.

§4 TSCA Order

Assessment of available information

The most significant route of exposure of PFASs, as it relates to direct health risks, is through ingestion from contaminated drinking water supplies. While the U.S. EPA has issued Drinking Water Health Advisories for PFSAs, the data available as it relates to PFASs human health implications though drinking water exposure is limited. As identified by the EPA Health Advisory, these limitations are due mainly to the confidentiality of geospatial data of U.S. drinking water supplies; the complete lack of information on PFASs in the drinking water for almost one-third of the U.S. population who obtain drinking water from smaller public water systems or private wells; and geospatial data lacked potentially important PFAS point sources such as a wide range of industries, landfills, biosolids application. Further, as the Danish EPA reported that for most short-chain PFASs, there is virtually no available health-related information; there is a general lack of specific experimental data; and the environmentally relevant physico-chemical data identified appeared somewhat inconsistent and confusing.

Testing Requested

To fully understand the potential for PFAS exposure from ground water and drinking water in the United States, a study design must include sampling of waters in the vicinity of manufacturing and processing facilities known as point source discharges of PFASs to the environment; Facilities where PFAS have been used (such as textile or carpet manufacturers) and may have resulted in contamination to soil and groundwater; and landfills where leaching of PFAS from disposal of products that contain it has resulted in, or may have a significant risk of, contamination to soil and groundwater.

The EPA maintains proper guidelines specific to sampling studies of chemical contaminants in treated drinking water and in drinking water sources for those contaminants within the scope of current regulatory monitoring, as well as guidance for chemical substances outside of this scope, such as *Sampling Guidance for Unknown Contaminants in Drinking Water.*[278] The EPA's Method 537, Rev. 1.1,[279] published in 2009, and the September 2016 Technical Advisory - Laboratory Analysis of Drinking Water Samples for Perfluorooctanoic Acid (PFOA) Using EPA Method 537 Rev. 1.1[280] can be used as guidance for developing the testing protocol.

---

[278] *Sampling Guidance for Unknown Contaminants in Drinking Water*, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, (February 2017), https://www.epa.gov/sites/production/files/2017-02/documents/sampling_guidance_for_unknown_contaminants_in_drinking_water_02152017_final.pdf.

[279] J.A. Shoemaker, P. Grimmett, and B. Boutin, *Determination of Selected Perfluorinated Alkyl Acids in Drinking Water by Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS),* UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, (September 2009), https://cfpub.epa.gov/si/si_public_record_report.cfm?direntryid=198984.

[280] *Technical Advisory – Laboratory Analysis of Drinking Water Samples for Perfluorooctanoic Acid (PFOA) Using EPA Method 537 Rev. 1.1.,* UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, (September 2016), https://www.epa.gov/sites/production/files/2016-09/documents/pfoa-technical-advisory.pdf

Attachment II

The OEC recognizes that we have provided an immense body of research throughout this petition. If the EPA would like access to the documents cited in this petition and is unable to access these documents using the citations provided throughout the petition, please let us know via email and we will assist you with finding the document of interest.

Trent Dougherty
General Counsel
The Ohio Environmental Council
1145 Chesapeake Avenue, Suite I
Columbus, OH 43212
tdougherty@theoec.org
(614) 487-7506

Chris Tavenor
Law Fellow
The Ohio Environmental Council
1145 Chesapeake Avenue, Suite I
Columbus, OH 43212
ctavenor@theoec.org
(614) 487-7506

EXHIBIT

C-128

Congress of the United States
Washington, DC 20515

July 17, 2018

The Honorable Andrew Wheeler
Acting Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460

Acting Administrator Wheeler:

We write to you about drinking water contamination from per- and polyfluorinated chemicals (PFAS) and the existing health advisory levels for PFOA and PFOS.

We are glad that after what seemed like a long delay, on June 20, 2018, a draft Toxicological Profile for PFAS written by the Agency for Toxic Substances and Disease Registry (ATSDR) was released to obtain public comment on its contents. Now that it has been released, we have heard suggestions that this draft study shows the U.S. Environmental Protection Agency's (EPA's) current health advisory levels for PFOA and PFOS in drinking water - set at 70 parts per trillion (ppt) - could be 7 to ten times higher than what ATSDR has preliminarily identified as the minimal risk level (MRL) for these chemicals.

According to the draft Toxicological Profile, exposure to PFOS and PFOA above the MRL might be associated with: pregnancy-induced hypertension/pre-eclampsia, liver damage, increases in total cholesterol and LDL cholesterol, increased risk of thyroid disease, decreased antibody response to vaccines, increased risk of decreased fertility; and decreases in birth weight.

In light of the potential serious health issues that could result from exposure to PFOS and PFOA above this draft MRL, we urge the U.S. Environmental Protection Agency (EPA) to review the final toxicological profile and, as appropriate, act immediately to adjust the health advisory levels for PFOS and PFOA.

In addition, the draft Toxicological Profile identified PFHxS and PFNA, additional types of PFAS, that are also potentially associated with health issues. Currently, there is no health advisory level for these chemicals. If warranted, the EPA should move to create health advisories for these additional chemicals.

We urge you to work with ATSDR as you develop toxicity values, analytical methods, and treatment options on PFAS for states, tribes, local governments, and health professionals.

While critical scientific inputs on PFAS are missing, the information that is currently out there is raising many public questions. The EPA should move quickly to make appropriate changes to the existing drinking water health advisories that effectively communicate and explain risks to the public, as well as provide tools for adequate protection from exposure to these chemicals.

Sincerely,

Daniel T. Kildee
MEMBER OF CONGRESS

Fred Upton
MEMBER OF CONGRESS

Brendan Boyle
MEMBER OF CONGRESS

Jack Bergman
MEMBER OF CONGRESS

Debbie Dingell
MEMBER OF CONGRESS

Brian Fitzpatrick
MEMBER OF CONGRESS

Brenda L. Lawrence
MEMBER OF CONGRESS

EXHIBIT

C-129

United States Senate
WASHINGTON, DC 20510

February 1, 2019

The Honorable Andrew Wheeler
Acting Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Dear Acting Administrator Wheeler:

We write to you regarding recent media reports citing that the Environmental Protection Agency (EPA) does not intend to establish enforceable drinking water standards for perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS) as part of the agency's national management plan for this class of chemicals. If this is accurate, EPA's inaction would be a major setback to states and affected communities. Therefore, we urge you to develop enforceable federal drinking water standards for PFOA and PFOS as well as institute immediate actions to protect the public from contamination from additional per- and polyfluoroalkyl substances (PFAS).

As you are aware, PFAS chemicals have emerged as a widespread contaminant in drinking water sources in several communities across the nation. While the risks associated with PFAS exposure are still being uncovered, studies have linked these unregulated emerging contaminants to a number of adverse health effects. On May 19, 2016, the EPA established lifetime health advisory levels for PFOA and PFOS. These health advisories, however, are non-enforceable and deprive states of much-needed federal guidance on how to determine and implement effective drinking water standards for PFOA and PFOS chemicals.

In the absence of federal standards, states have been forced to create their own drinking water regulations for PFAS. This uncoordinated process has led to a patchwork of conflicting drinking water standards and guidelines in nine states with widely varying maximum contaminant levels. Moreover, the varying levels of standards have caused confusion among regulated entities and affected communities who wonder if their regulations are sufficient.

Federal safe drinking water standards are critical to addressing public concerns and allow for states to focus their efforts and limited resources on implementation and compliance assurance. Without enforceable drinking water standards for PFOA and PFOS, it is doubtful that a national management strategy will sufficiently confront the challenges PFAS chemicals pose to states and affected communities. This decision would also fail to consider ongoing interagency efforts to determine the human health implications of contamination from PFAS, including the nationwide study being conducted by the Agency for Toxic Substances and Disease Registry (ATSDR).[1] We urge you to ensure that EPA's National PFAS Management Plan includes a commitment to

[1] The National Defense Authorization Acts for 2018 and 2019 authorized a transfer of funds from the Department of Defense to ATSDR to study PFAS exposure and related human health outcomes. This includes exposure assessments, community engagement, a health study at Pease International Tradeport in New Hampshire and a national multi-site health study.

develop federal drinking water standards for PFOA and PFOS, pursuant to the Safe Drinking Water Act. We also request that EPA provide briefings to our offices on the agency's efforts on this issue, as well as regular updates on the progress of those efforts.

Safe drinking water is essential to the health and well-being of every American. And while our nation's water quality is among the highest in the world, we now face a serious challenge: aggressively addressing the health and environmental threats connected with PFAS. We believe it is imperative that the EPA show leadership and help protect American families from these harmful materials. We thank you for your attention to this important matter and look forward to your timely response.

Sincerely,

JEANNE SHAHEEN
United States Senator

SHELLEY MOORE CAPITO
United States Senator

MARGARET WOOD HASSAN
United States Senator

DEBBIE STABENOW
United States Senator

THOMAS R. CARPER
United States Senator

TOM UDALL
United States Senator

MARIA CANTWELL
United States Senator

PATTY MURRAY
United States Senator

ROBERT P. CASEY, JR.
United States Senator

PATRICK LEAHY
United States Senator

JACK REED
United States Senator

MARTIN HEINRICH
United States Senator

SHERROD BROWN
United States Senator

BERNARD SANDERS
United States Senator

JOE MANCHIN III
United States Senator

ROBERT MENENDEZ
United States Senator

KIRSTEN GILLIBRAND
United States Senator

ELIZABETH WARREN
United States Senator

GARY C. PETERS
United States Senator

THOM TILLIS
United States Senator

EXHIBIT

C-130

United States Senate
WASHINGTON, DC 20510

March 6, 2019

The Honorable Andrew Wheeler
Administrator
U.S. Environmental Protection Agency (EPA)
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Dear Administrator Wheeler,

We write to request information related to EPA's nationwide PFAS Action Plan and other related actions. The PFAS Action Plan, which EPA released on February 14, 2019, did not include a commitment to promulgate a drinking water standard for PFOA and PFOS. EPA also failed to release its groundwater cleanup guidelines for PFOS and PFOA in tandem with the PFAS Action Plan, despite announcing[1] that it would complete these guidelines by Fall, 2018.

The Office of Management and Budget, the Department of Health and Human Services, and Department of Defense all participated in the interagency review of EPA's PFAS Action Plan. It is also our understanding that the groundwater cleanup guidelines for PFOS and PFOA have been held up at OMB since August 2018 due to an interagency dispute[2] related to how stringent the guidelines should be. Finally, we have also been informed that in at least one instance, the United States Air Force has diverted funds intended for a site cleanup of non-PFAS contamination to PFAS-related cleanup efforts.

So that we may better understand the views of the Agencies involved in the finalization of the PFAS Action Plan and groundwater cleanup guidelines, please provide us with responses to the following requests by March 22, 2019:

1. Copies of all documents exchanged between EPA and DOD regarding the PFAS Action Plan or the groundwater cleanup guidelines for PFOS and PFOA.
2. Copies of all documents exchanged between EPA and OMB regarding the PFAS Action Plan or the groundwater cleanup guidelines for PFOS and PFOA.
3. Copies of all documents exchanged between EPA and HHS regarding the PFAS Action Plan or the groundwater cleanup guidelines for PFOS and PFOA.

For purposes of this letter, "documents" includes, but is not limited to, comments, notes, emails, legal and other memoranda, white papers, scientific references, letters, telephone logs, text messages, meeting minutes and calendars, photographs, slides and presentations. In the case of

[1] https://www.epa.gov/newsreleases/administrator-pruitt-kicks-national-leadership-summit-pfas
[2] https://subscriber.politicopro.com/energy/article/2019/01/epa-ignores-cdc-guidelines-in-chemical-cleanup-plan-1067544

meetings, calls, or other oral communications, please include the date, time, and location at which such communications took place, a list of the individuals who participated, as well as a description of the communication.

Thank you for your prompt attention to these requests. If you or members of your staff have any questions regarding these requests please contact Michal Freedhoff on the Environment and Public Works Committee staff at 202-224-8832, Yogin Kothari on the Homeland Security and Governmental Affairs Committee staff at 202-224-2627, Elizabeth Letter on the Health, Education, Labor and Pensions Committee staff at 202-224-0767, or John Quirk on the Armed Services Committee staff at 202-224-8625.

Sincerely yours,

Tom Carper
Ranking Member
Environment and Public
Works Committee

Patty Murray
Ranking Member
Health, Education, Labor and
Pensions Committee

Gary C. Peters
Ranking Member
Homeland Security and
Governmental Affairs
Committee

Jack Reed
Ranking Member
Armed Services Committee

EXHIBIT

C-131

United States Senate

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
WASHINGTON, DC 20510-6175

March 13, 2019

The Honorable Andrew Wheeler
Administrator
U.S. Environmental Protection Agency (EPA)
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Dear Administrator Wheeler,

I write with grave concerns regarding the delay in the finalization of EPA's groundwater cleanup guidelines for PFOS and PFOA, two types of per- and poly-fluoroalkyl substances (PFAS). These guidelines have been held up at OMB since August 2018 due to an interagency dispute[1] related to determining the stringency of the guidelines. Specifically, I have learned that the reason for the lengthy delay is that the Department of Defense (DOD), National Aeronautics and Space Administration (NASA) and the Small Business Administration (SBA) are urging for the adoption of a much less stringent clean-up standard. I urge you to resist these or any other efforts to weaken the clean-up standards and quickly finalize guidelines that are sufficiently protective of human health and the environment.

EPA is currently developing its Interim Recommendations for Addressing Groundwater Contaminated with PFOA and PFOS to help provide support to site-specific cleanup efforts, including efforts at military and other federal sites. According to a March 2018 DOD presentation[2] to Congress, DOD identified 90 military installations and 1,621 groundwater wells whose levels of PFOA and PFOS exceeded EPA's drinking water lifetime health advisory of 70 parts per trillion (ppt). EPA's groundwater cleanup guidelines would be expected to be used as base standards for remediation of contamination at these and other sites. In May 2018, former Administrator Scott Pruitt announced[3] that EPA would complete these guidelines by fall 2018, but they have neither been released for public comment nor finalized.

My office has recently obtained some disturbing information that may be related to the reasons for the delay in the release of these guidelines:

- My office has been informed that EPA's draft proposed guidelines recommended that contaminated sites be cleaned up to a level equivalent to EPA's current drinking water lifetime health advisory of 70 ppt of PFOA/PFOS. Additionally, EPA recommended that emergency measures, such as the provision of alternative drinking water, be taken when levels of PFOA/PFOS exceed 400 ppt.

- According to sources, DOD, along with NASA and SBA, have objected to EPA's proposed clean up and emergency levels. These agencies instead urged for the adoption of a much higher 400 ppt clean-up standard and 1200 ppt emergency level. Such levels would, among other consequences, subject fewer sites that were contaminated through the military's use of PFOA/PFOS from having to be remediated in the first place. Additionally, although EPA recommended that the clean-up and

[1] https://subscriber.politicopro.com/energy/article/2019/01/epa-ignores-cdc-guidelines-in-chemical-cleanup-plan-1067544
[2] https://partner-mco-archive.s3.amazonaws.com/client_files/1524589484.pdf
[3] https://www.epa.gov/newsreleases/administrator-pruitt-kicks-national-leadership-summit-pfas

emergency levels be triggered by individual *or* combined levels of PFOA and PFOS (such that, for example, 25 ppt of PFOA and 50 ppt of PFOS would combine to exceed EPA's proposed 70 ppt clean-up level), some or all of DOD, NASA and SBA may have opposed this recommendation to combine the levels of exposure of individual PFAS chemicals. These agencies instead may have recommended that each PFAS chemical be treated separately, which could mean, for example, that a site that includes levels of 399 ppt each of PFOA and PFOS (for a combined level of 798 ppt, more than ten times EPA's lifetime health advisory level) would be excluded from clean-up and emergency remediation efforts.

- EPA has reportedly resisted these weakening measures. However, my office has learned that DOD and NASA continue to refuse to agree to take any measures to remediate contamination caused by their activities unless the measured levels of PFOA and PFOS exceed 400 ppt. Once such levels are exceeded these Agencies reportedly will agree to clean the contamination down to a level of 70 ppt. However, for any contamination whose PFOA and PFOS levels are under 400 ppt (including contamination that has migrated off the federal sites into the surrounding communities), no action would be taken at all. This means that people who live both on and off contaminated federal sites would not be assured of protection from contamination well in excess of the 70 ppt level that EPA has said[4] is needed to "provide Americans, including the most sensitive populations, with a margin of protection from a lifetime of exposure to PFOA and PFOS from drinking water."

In your confirmation hearing, you said that "It is these Americans that President Trump and his Administration are focused on, Americans without access to safe drinking water or Americans living on or near hazardous sites, often unaware of the health risks they and their families face. Many of these sites have languished for years, even decades. How can these Americans prosper if they cannot live, learn, or work in healthy environments?" Please take prompt action to finalize groundwater clean-up guidelines for PFAS that live up to your stated objectives and reject efforts by other federal agencies to weaken them.

Thank you for your prompt attention to this matter. If you or members of your staff have any questions regarding these requests, please ask your staff to contact Michal Freedhoff of the Environment and Public Works Committee staff at 202-224-8832.

Sincerely yours,

Tom Carper
Ranking Member

[4] https://www.epa.gov/ground-water-and-drinking-water/drinking-water-health-advisories-pfoa-and-pfos

EXHIBIT

C-132

June 10, 2019

The Honorable John Barrasso
Chairman
Committee on Environment and Public Works
United States Senate
307 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Tom Carper
Ranking Member
Committee on Environment and Public Works
United States Senate
513 Hart Senate Office Building
Washington, DC 20510

RE: Federal Action on PFAS

Dear Chairman Barrasso and Ranking Member Carper:

The Northeast Committee on the Environment (NECOE) brings together environmental commissioners from all six New England states – Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont – and New York in order to work together and find solutions to environmental challenges facing our region.

As you know, per- and polyfluoroalkyl substances (PFAS) are a group of compounds resistant to heat, water, and oil. For decades, they have been used in hundreds of industrial applications and consumer products such as carpeting, apparel, upholstery, food paper wrappings, fire-fighting foams and metal plating. The Northeast has been at the forefront of this issue due to early detections of PFAS contamination in Vermont, New York, and New Hampshire. As the chair and ranking member of the U.S. Senate Committee on Environment and Public Works (EPW), we are writing to support your work and require immediate federal action on five specific matters.

First, EPA should establish a national maximum contaminant level (MCL) that fully protects the public health from PFAS exposure in drinking water as soon as possible. In the absence of federal leadership, many states are moving ahead with establishing their own drinking water standards and guidance. It is evident in the May 22, 2019 EPW hearing, which examined all six legislative bills proposed to address the risks associated with PFAS, that this is a national concern. Collectively these bills represent a significant start to Congressional efforts to deal with these serious contaminants.

Second, given that PFAS constitute a class of compounds with common characteristics, we believe they should be regulated accordingly. Developing and implementing individualized approaches to the regulation of each of the thousands of PFAS chemical formulations is impracticable, unnecessary and inconsistent with the need for swift

action. We ask that the EPW support and recommend a class-based approach to PFAS regulation at the federal level.

Third, the demands on our states to test various environmental media for PFAS contamination, and to remediate contaminated sites, are increasing dramatically. We request a corresponding increase in access to federal funds to perform this work. Toward that end, we ask that the EPW require the EPA to amend its regulations to treat PFAS compounds as hazardous substance under CERCLA, make available low-cost supplemental loans for regional cleanup efforts using a model similar to the Water Infrastructure and Innovation Act, and fully fund the important research necessary to ensure that EPA and the States can appropriately manage risks associated with PFAS and other emerging contaminants.

Fourth, complicating these demands on states is the need for uniform federal laboratory methods for PFAS analysis in surface water, groundwater, soil, sediment and air, which are important to consistently and accurately quantify the impacts of PFAS on human health and the environment. There exists, moreover, a similar need for PFAS treatment technologies for soil and air, especially at facilities that continue to manufacture PFAS-containing products. We ask that the EPW urge EPA to expedite the development and dissemination of analytical methods and treatment technologies that extend beyond drinking water.

Finally, but importantly, we strongly urge more aggressive and responsible federal regulation of the use of PFAS compounds and other emerging contaminants throughout our economy. We ask that the EPW support and recommend that EPA address source control and minimize or eliminate outright the use of PFAS compounds in commercial and industrial applications.

Thank you for your work on these important issues and for your consideration of our requests.

Sincerely,

Katie Dykes
Commissioner
Connecticut Department of Energy and Environmental Protection

Jerry Reid
Commissioner
Maine Department of Environmental Protection

→

Martin Suuberg
Commissioner
Massachusetts Department of Environmental Protection

Robert Scott
Commissioner
New Hampshire Department of Environmental Service

Basil Seggos
Commissioner
New York State Department of Environmental Conservation

Janet Coit
Director
Rhode Island Department of Environmental Management

Julie Moore
Secretary
Vermont Agency of Natural Resources

cc: Senate Minority Leader Chuck Schumer
Senator Richard Blumenthal
Senator Chris Murphy
Senator Elizabeth Warren
Senator Ed Markey
Senator Susan Collins
Senator Angus King
Senator Maggie Hassan
Senator Jeanne Shaheen
Senator Kirsten Gillibrand
Senator Jack Reed
Senator Sheldon Whitehouse
Senator Bernie Sanders
Senator Patrick Leahy

EXHIBIT

C-133

ATTORNEYS GENERAL OF NEW YORK, CALIFORNIA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, GUAM, HAWAI'I, ILLINOIS, IOWA, MAINE, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MISSISSIPPI, NEW JERSEY, NEW MEXICO, OREGON, RHODE ISLAND, VIRGINIA, WASHINGTON, AND WISCONSIN

July 30, 2019

The Honorable Mitch McConnell
Majority Leader
United States Senate
317 Russell Senate Office Building
Washington, D.C. 20510

Honorable Charles E. Schumer
Minority Leader
United States Senate
322 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Nancy Pelosi
Speaker
United States House of Representatives
1236 Longworth House Office Building
Washington, D.C. 20515

The Honorable Kevin McCarthy
Minority Leader
United States House of Representatives
2468 Rayburn House Office Building
Washington, D.C. 20515

Re: PFAS Legislation

Dear Majority Leader McConnell, Minority Leader Schumer, Speaker Pelosi, and Minority Leader McCarthy:

As the United States Congress moves forward to address the threat to human health and the environment posed by the class of chemical compounds known as poly- and per-fluoroalkyl substances ("PFAS"), we write to urge Congress to ensure that some of the most urgent legislative needs – based on our experiences in our respective jurisdictions – are addressed.

PFAS have been used to produce countless products since the 1940s, including textiles with Scotchgard; Teflon products, including non-stick cookware; and food packaging. PFAS have also been used for decades as ingredients in firefighting foam, which has been used across

the country, including by the U.S. military and local fire departments. While PFAS are entirely human-made, they are estimated to be detectable in the blood stream of approximately 99% of the U.S. population. PFAS are known as "forever chemicals" because they resist degradation in the environment. PFAS also bioaccumulate – and are toxic – to humans and animals. Although scientific knowledge regarding PFAS is still developing, PFAS are linked to serious adverse health effects in humans and animals. The two most studied types of PFAS are known by the acronyms PFOA and PFOS. Human health effects associated with exposure to PFOA include kidney and testicular cancer, thyroid disease, liver damage, and preeclampsia; exposure to PFOS is associated with immune system effects, changes in liver enzymes and thyroid hormones, and other conditions.[1]

Many of the signatories to this letter face substantial PFAS issues in their jurisdictions, while others are just beginning to investigate the extent of PFAS contamination in their States. In jurisdictions that have already identified significant PFAS contamination within their borders, we are spending tens of millions of dollars to address contamination in public drinking water sources and to investigate numerous areas of potential contamination across our communities and to prioritize responses to such contamination. Contaminated sites in our jurisdictions include but are not limited to military bases where firefighting foam was used, firefighting training centers, civilian airports, and industrial facilities.

Although eventually Congress will likely need to address the entire PFAS "lifecycle"– production, use, exposure, cleanup, and disposal – we applaud the Senate and the House of Representatives for advancing legislation that address particular issues associated with PFAS contamination. As Congress moves to reach agreement on final legislation, the experiences of our States in responding to the dangers of PFAS point to several immediate legislative needs. For the reasons set forth below, we urge Congress to support the following necessary first steps in addressing the problems posed by PFAS. Any legislation, of course, should not impair the existing rights of States to pursue appropriate remedies under existing law.

CERCLA Designation

Designate certain PFAS as "hazardous substances" under the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA").[2] This designation should include but not be limited to PFOA, PFOS, and "GenX" PFAS. Additionally, the Environmental Protection Agency ("EPA") should be directed to immediately study other PFAS and to designate all or some of the substances in the PFAS class of chemical compounds as hazardous substances under CERCLA. Such designation will help promote cleanup of some of the worst contaminated sites in the country that pose substantial threats to human health and/or the environment, including sites currently or formerly owned or operated by the U.S. Department of Defense ("DOD"). To date, DOD has identified over 400 federal facilities around the country with known or suspected PFAS contamination from firefighting foam.[3] DOD has resisted cleanup of federal facilities around the country, however, on the basis that PFAS are not

[1] *See, e.g.*, C8 Science Panel Website, http://www.c8sciencepanel.org/.
[2] 42 U.S.C. §§ 9601-9675.
[3] *See* U.S. Gov't Accountability Office, GAO-18-700T, *Status of DOD Efforts to Address Drinking Water Contamination Used in Firefighting Foam* (2018), *available at* www.gao.gov/products/GAO-18-700T.

hazardous substances under CERCLA or otherwise federally regulated. Because CERCLA applies to facilities owned or operated by the federal government,[4] a designation of certain PFAS as hazardous substances under CERCLA would promote the appropriate cleanup of these sites. A designation under CERCLA would also promote cleanup of so-called "orphan" sites where responsible parties cannot be identified or located, or they fail to act. Contaminated sites that are subject to CERCLA would be cleaned up in a manner consistent with CERCLA's well-established procedures and protocols.[5] Legislative carve-outs under CERCLA for certain other types of facilities could be provided, as appropriate.

CERCLA also provides reporting requirements for releases of hazardous substances over certain thresholds, and that reporting will facilitate investigations and potential cleanups of federal facilities and other sites across the country.[6] EPA should also be directed to develop appropriate analytical methodologies for testing for PFAS in various environmental media.

Inclusion in the Toxic Release Inventory ("TRI") Maintained by EPA

Add the entire class of PFAS to EPA's TRI.[7] This would provide information about new potential sources and areas of contamination. The thresholds for reporting releases of PFAS to the TRI should be set at a very low level, to account for the fact that PFAS may be toxic in very low concentrations.

Sampling and Survey of PFAS Contamination by the U.S. Geological Survey ("USGS")

Direct the USGS to conduct a nationwide sampling effort and survey of human and environmental exposure to PFAS, with an emphasis on drinking water, to determine the scope of PFAS contamination. This information will assist all stakeholders in prioritizing areas that require further response and will complement the inclusion of PFAS on EPA's TRI. Our respective States' jurisdictional agencies stand ready to assist the federal government in identifying the locations that should be the highest priority for investigation.

Funding for Communities' Response to PFAS Contamination

Provide funding for remediation of public water systems, with a focus on environmental justice and other disadvantaged communities. Many public water providers do not have sufficient funding to address PFAS contamination, and even when they may in the first instance, raising water rates to recoup those costs present serious water affordability issues. Funding should also be made available to address potential contamination of private drinking water sources.

---

[4] *See* 42 U.S.C. §§ 9601(21), 9620.
[5] *See* 40 C.F.R. Part 300.
[6] *See* 42 U.S.C. § 9603; 40 C.F.R. Part 302.4.
[7] *See* 42 U.S.C. § 11023.

Prohibit the Use and Storage of Firefighting Foam Containing PFAS at U.S. Military Bases and Other Federal Facilities

Prohibit the use and storage of firefighting foam containing PFAS at United States military bases and other federal facilities as quickly as possible, and immediately require protective measures when firefighting foam is used. Aqueous film-forming foam, or AFFF, is directly sprayed on or near the ground when it is used, and it is the source of PFAS at some of the worst contaminated areas in the nation, including at numerous military sites. Some of our jurisdictions have been forced to spend tens of millions of dollars to provide vulnerable communities near military bases with uncontaminated water and filtration systems. While AFFF may be discharged into the environment in responding to emergencies (or may be discharged accidentally), the vast majority of AFFF is used for firefighting training. Congress should require that training foams that do not contain PFAS be used instead of AFFF containing PFAS, and that barriers or other measures be used in areas in which foam is discharged to prevent potential contamination of the environment.

Medical Screening

Provide for medical screening for PFAS exposure for appropriate personnel and members of the public who may have been exposed to PFAS, including but not limited to firefighting personnel. Our citizens deserve to know about potential health threats, particularly those incurred on the job.

* * *

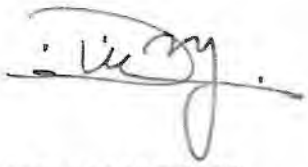
Public understanding about the serious risks that PFAS contamination poses to human health and the environment is growing. Without federal legislative action to assist States and communities that are responding to this burgeoning threat, the public may lose confidence in the safety of its drinking water sources, consumer products, and other routes of exposure to dangerous levels of PFAS. We applaud the Senate and the House of Representatives for recognizing the dangers of PFAS and advancing legislation to address the resulting public health concerns and mounting State and local response costs. We urge Congress to continue these efforts by supporting the initial legislative needs highlighted above as Congress moves to reach agreement on final legislation addressing PFAS contamination.

Thank you for your time and consideration of these urgent matters.

Sincerely,

LETITIA JAMES
Attorney General of New York

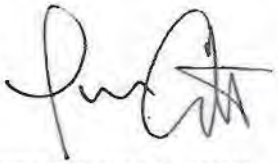
XAVIER BECERRA
Attorney General of California



WILLIAM TONG
Attorney General of Connecticut

KATHLEEN JENNINGS
Attorney General of Delaware

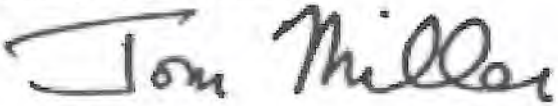
KARL A. RACINE
Attorney General of District of Columbia



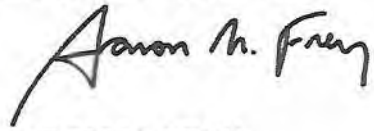
LEEVIN CAMACHO
Attorney General of Guam

CLARE E. CONNORS
Attorney General of Hawai'i

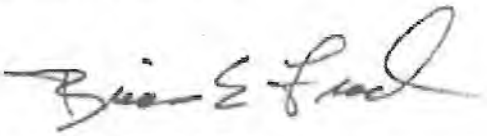
KWAME RAOUL
Attorney General of Illinois



TOM MILLER
Attorney General of Iowa

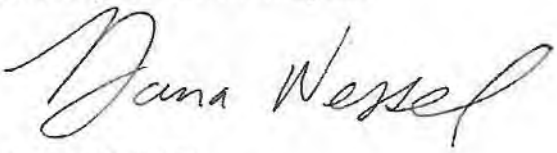


AARON M. FREY
Attorney General of Maine

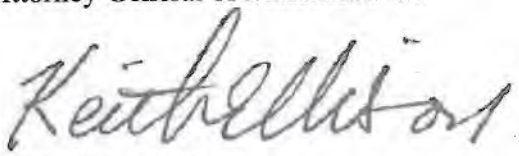


BRIAN E. FROSH
Attorney General of Maryland

MAURA HEALEY
Attorney General of Massachusetts



DANA NESSEL
Attorney General of Michigan



KEITH ELLISON
Attorney General of Minnesota

JIM HOOD
Attorney General of Mississippi

GURBIR S. GREWAL
Attorney General of New Jersey

HECTOR BALDERAS
Attorney General of New Mexico

ELLEN ROSENBLUM
Attorney General of Oregon

PETER F. NERONHA
Attorney General of Rhode Island

MARK R. HERRING
Attorney General of Virginia

BOB FERGUSON
Attorney General of Washington

JOSHUA L. KAUL
Attorney General of Wisconsin

Cc: Sen. John Barrasso, Chairman, Senate Committee on Environment and Public Works
Sen. Thomas R. Carper, Ranking Member, Senate Committee on Environment and Public Works
Rep. Frank Pallone, Jr., Chairman, House Committee on Energy and Commerce
Rep. Greg Walden, Ranking Member, House Committee on Energy and Commerce
Sen. James Inhofe, Chairman, Senate Committee on Armed Services
Sen. Jack Reed, Ranking Member, Senate Committee on Armed Services
Rep. Adam Smith, Chairman, House Committee on Armed Services
Rep. Mac Thornberry, Ranking Member, House Committee on Armed Services
Rep. Raul M. Grijalva, Chairman, House Committee on Natural Resources
Rep. Rob Bishop, Ranking Member, House Committee on Natural Resources
Rep. Peter A. DeFazio, Chairman, House Committee on Transportation and Infrastructure
Rep. Sam Graves, Ranking Member, House Committee on Transportation and Infrastructure
Rep. Brian Fitzpatrick, Chairman, Congressional PFAS Task Force
Rep. Dan Kildee, Chairman, Congressional PFAS Task Force

EXHIBIT

C-134

September 18, 2019

The Honorable James Inhofe
Chairman
Senate Armed Services Committee
218 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Adam Smith
Chairman
House Armed Services Committee
2216 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Jack Reed
Ranking Member
Senate Armed Services Committee
218 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Mac Thornberry
Ranking Member
House Armed Services Committee
2216 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Inhofe, Ranking Member Reed, Chairman Smith and Ranking Member Thornberry:

As you instruct your conferees to consider the Fiscal Year (FY) 2020 National Defense Authorization Act (NDAA), we, the undersigned governors, would like to highlight several key provisions related to per- and polyfluoroalkyl substances (PFAS) and urge you to include them in the final legislation.

PFAS are used in many nonstick coatings in consumer products, industrial processes, and firefighting foams often used by the military and at airports. These chemicals, which break down extremely slowly or not at all, can accumulate in our environment and in our bodies, and those that have been studied are associated with adverse health effects, such as liver damage, thyroid disease, and kidney and testicular cancers. Provisions in the current House and Senate measures will ensure the U.S. Department of Defense (DoD) mitigates the impacts of PFAS contamination, require the U.S. Environmental Protection Agency (EPA) to move more quickly to set PFAS health standards and protections, and provide much-needed resources and guidance as the federal government, states, and communities work to address contamination from these persistent substances.

At current and former military bases across the country, firefighting foam containing PFAS has been in use for many years to meet FAA firefighting standards at FAA controlled airports, and by extension at military airports. In many of these locations, PFAS have leached into groundwater, surface water, and

nearby private wells used for drinking water. According to the Government Accountability Office, there are at least 401 military sites with known or suspected PFAS contamination.[1]

As governors, we are evaluating responses appropriate for our states, including in some cases developing or setting drinking water standards for PFAS, and deploying state funds to test, investigate, and remediate PFAS contamination caused by government and industrial uses. Nevertheless, federal action is needed to address PFAS, including contamination in and around military sites.

Our Congressional delegations have worked diligently to include important provisions in the House and Senate bills to require the DoD and EPA to investigate, monitor and clean up PFAS contamination originating from DoD activities. It is clear that many members of Congress on both sides of the aisle understand the urgent need to act to address these toxic PFAS chemicals. As governors whose residents are affected by these toxics, we urge development of a package that includes the strongest provisions from both the House and Senate bills, including the following that would:

- Require EPA to set an enforceable, nationwide drinking water standard under the Safe Drinking Water Act for PFOA and PFOS within two years of enactment, while preserving states' authority to enact their own, more stringent standards.
- Require the EPA to list PFAS chemicals as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) within one year.
- Require the EPA to revise the list of toxic pollutants under the Federal Water Pollution Control Act (commonly known as the Clean Water Act) to include PFAS and publish effluent and pretreatment standards.
- Phase out the use of PFAS in aqueous film forming foam (AFFF) as quickly as possible.
- Urge the DoD to finalize cooperative agreements with states and partner with governors to test, monitor, remove, and remediate PFAS contamination originating from DoD activities, including at decommissioned military installations and National Guard facilities. Require that if a cooperative agreement is not reached within one year of the request from a state, the Secretary of Defense must report to Congress with an explanation of why an agreement has not been reached. Remediation should satisfy both federal and state/local remediation targets.
- Grant the National Guard Bureau access to specific environmental remediation program funding in FY 2020.
- Authorize the U.S. Geological Survey (USGS) to develop advanced testing methods capable of detecting PFAS, and to conduct nationwide sampling for these chemicals – focusing first on areas near drinking water with known or suspected PFAS contamination.
- Require the DoD to treat and clean PFAS-contaminated water used for agricultural purposes.
- Require public disclosure, as part of Toxic Release Inventory (TRI) annual reports, when environmental releases of about 200 PFAS chemicals occur – including PFOS and PFOA.

The FY2020 NDAA presents an opportunity to take historic steps forward to address PFAS contamination that is harming our states, and we ask you to include the strongest PFAS-related provisions in the final bill.

Sincerely,

[1] https://www.gao.gov/products/GAO-18-700T

Governor Gretchen Whitmer
State of Michigan

Governor John Carney
State of Delaware

Governor Charlie Baker
Commonwealth of Massachusetts

Governor Tim Walz
State of Minnesota

Governor Chris Sununu
State of New Hampshire

Governor Phil Murphy
State of New Jersey

Governor Michelle Lujan Grisham
State of New Mexico

Governor Andrew Cuomo
State of New York

Governor Roy Cooper
State of North Carolina

Governor Mike DeWine
State of Ohio

Governor Tom Wolf
Commonwealth of Pennsylvania

Governor Phil Scott
State of Vermont

Governor Ralph Northam
Commonwealth of Virginia

Governor Jay Inslee
State of Washington

Tony Evers

Governor Tony Evers
State of Wisconsin

EXHIBIT

C-135

United States Senate
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
WASHINGTON, DC 20510–6175

May 21, 2020

The Honorable Andrew Wheeler
Administrator
U.S. Environmental Protection Agency (EPA)
1301 Constitution Ave. NW
Washington, DC 20460

Dear Administrator Wheeler,

We write to request information about EPA's plan to address per- and polyfluoroalkyl substances (PFAS) contamination at Superfund sites. We are particularly interested in the 180 Superfund sites EPA has identified as containing PFAS that were provided to the Senate Environment and Public Works (EPW) Committee in responses to questions posed at a 2019 hearing.[1] While it is helpful to know where these substances have been found, EPA did not include information as to which specific PFAS were found at each site, or the amount of those chemicals present. This information is critical to the continued response to PFAS contamination, as well as to efforts to ensure the public health and safety of the 53 million Americans that live within three miles of a Superfund site.[2]

As part of Assistant Administrator David Ross's response to questions for the record from Ranking Member Carper during the EPW Committee's March 2019 hearing entitled *"Examining the federal response to the risks associated with per- and polyfluoroalkyl substances (PFAS)."* EPA identified and shared a list of 180 Superfund sites where PFAS have been detected. This response provided no information as to the level of contamination that was identified at each site. The 180 sites have been plotted on a map, available as an attachment to this document or by following the link to the interactive map,[3] and include Superfund sites in 33 states and the District of Columbia.

In the Interim Recommendations for Addressing Groundwater Contaminated with PFOA and PFOS submitted to OMB on August 31, 2018,[4] EPA sought to establish a screening level of 40

[1] Our request comes as a direct response to information Mr. Ross, Assistant Administrator of the Office of Water, provided as part of his answers to Questions for the Record for the Senate Committee on Environment and Public Works Hearing entitled, *"Examining the federal response to the risks associated with per- and polyfluoroalkyl substances (PFAS)"* on March 28, 2019.
[2] https://www.epa.gov/sites/production/files/2015-09/documents/webpopulationrsuperfundsites9.28.15.pdf
[3] Link to map of Superfund Sites Identified by EPA to have PFAS Contamination: https://www.epw.senate.gov/public/index.cfm?p=Superfund-Sites-Identified-by-EPA-to-have-PFAS-Contamination
[4] https://www.regulations.gov/document?D=EPA-HQ-OLEM-2019-0229-0003

parts per trillion (ppt). At that time, EPA recommended that any detection of PFAS at or above that level warranted further investigation.

Additionally, Mr. Ross's response states that for Superfund sites where the presence of PFAS exceeds the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) screening levels of 40 ppt, "the site will be monitored along with other contaminants throughout the remediation process." However, Mr. Ross did not indicate whether the agency would ensure the remediation of current or potential sources of drinking water contamination at these sites to bring them into compliance with EPA's drinking water health advisory, which recommends an individual or combined standard of 70 ppt.[5]

Mr. Ross was also asked whether EPA had tested all Superfund sites for the presence of PFAS. Mr. Ross answered that at this time "the agency has only tested Superfund sites where there is reason to believe PFAS chemicals might be present," and that testing "generally occurs as part of the site investigation, a five-year review, or as part of remedy optimization." Given the widespread use and persistent nature of PFAS, additional efforts to test for PFAS at Superfund sites may be warranted.

So that we can further understand the information EPA has collected regarding the presence of PFAS contamination at Superfund sites, as well as the agency's plan to address it, we ask that you provide us with responses to the following questions and requests for information by June 19th, 2020.

1. Please identify all Superfund sites that have been found to contain PFAS, along with a list of each specific PFAS detected and the level (in ppt) at which it was found. If comprehensive monitoring at all Superfund sites has not been undertaken in a manner that obtained this information, please describe EPA's plans for doing so along with a timeline for its completion.

2. Please provide information as to how the presence of PFAS identified during the preliminary assessment or site inspection is incorporated into EPA's Hazard Ranking System. Does it contribute to the overall score necessary for a site to receive listing on the National Priorities List, and if so, how? Would this process be expected to change for PFAS designated to be hazardous substances under CERCLA, and if so, how?

3. Please provide information as to how the Remedial Investigation process is used to determine the nature and extent of PFAS contamination at a Superfund site, as well as how that information is shared with the public during the Remedial Investigation and Feasibility Study phase of the Superfund cleanup process. Would this process be expected to change for PFAS designated to be hazardous substances under CERCLA, and if so, how?

[5] https://www.regulations.gov/document?D=EPA-HQ-OLEM-2019-0229-0003

4. Please provide a list of Superfund sites for which the Record of Decision issued by the agency addressed PFAS contamination, and a description of how it was addressed.

5. For Superfund sites where PFAS are known to be present, but a plan for their removal or remediation was not included in the original Record of Decision, please provide information as to whether the agency plans to reopen those cleanup agreements and amend them to include the removal or remediation of PFAS at Superfund sites. Would this process be expected to change for PFAS designated to be hazardous substances under CERCLA, and if so, how?

6. Under CERCLA, please describe whether EPA has the authority to:

    a. Require the cleanup of PFOS or PFOA if they are present at levels higher than 70 ppt at a Superfund site.
    b. Require the cleanup of PFOS or PFOA if there has been, or could be, a release of PFOS or PFOA from the site.
    c. Recover response costs for the remediation of PFOS and PFOA from the potentially responsible party if such costs have been or will be incurred by the government or other parties.
    d. Use EPA's de minimis settlement authority or other tools to compel or facilitate settlements with potentially responsible parties to address contamination by PFOA or PFOS.

    For each of a-d above, please also describe how EPA's authority would change if PFOS and PFOA are designated as hazardous substances under CERCLA.

Thank you for your prompt attention to this matter. If you or members of your staff have any questions regarding these requests, please ask the appropriate members of your staff to contact Michal Freedhoff or Annie D'Amato of the EPW Committee staff at 202-224-8832.

Sincerely yours,

Thomas R. Carper
Ranking Member

Benjamin L. Cardin
United States Senator

Bernard Sanders
United States Senator

Sheldon Whitehouse
United States Senator

Jeffrey A. Merkley
United States Senator

Kirsten Gillibrand
United States Senator

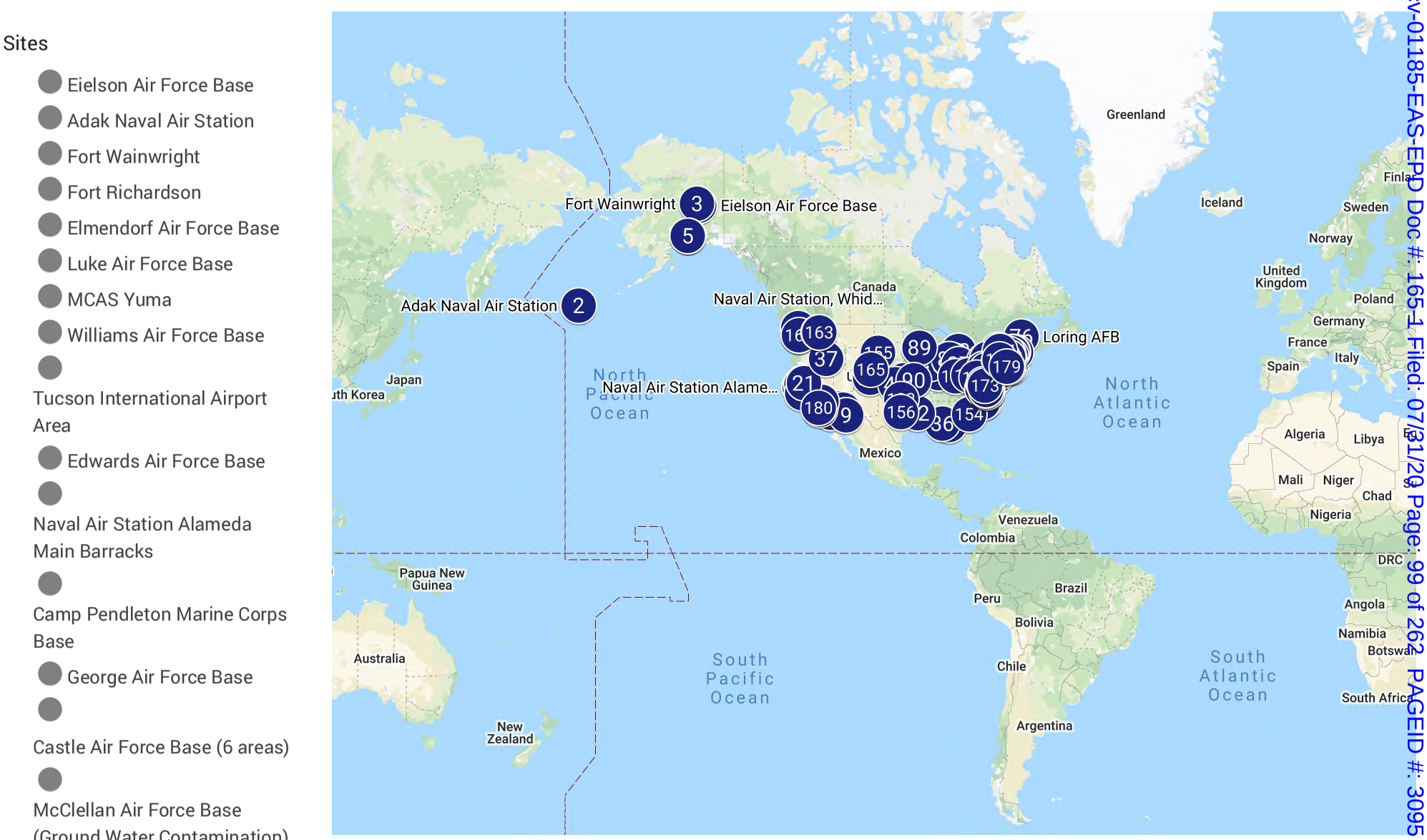
Cory A. Booker
United States Senator

Edward J. Markey
United States Senator

Tammy Duckworth
United States Senator

Chris Van Hollen
United States Senator

Superfund Sites Identified by EPA to have PFAS Contamination



- Charts superfund sites where, per EPA, PFAS contamination has been detected.

Norton Air Force Base (Landfill 2)

March Air Force Base

Travis Air Force Base

Fort Ord

Barstow Marine Corps Logistics Base

Mather Air Force Base (AC&W Disposal SIte)

Air Force Plant PJKS

Solvents Recovery Service of New England

Precision Plating Corporation

Beacon Heights Landfill

Gallup's Quarry

Laurel Park, Inc.

Kellogg-Deering Well Field

New London Submarine Base

Washington Navy Yard

Dover Air Force Base

Delaware Sand & Gravel Landfill

Army Creek Landfill

Blades Groundwater

Tyndall Air Force Base

Pensacola Naval Air Station

- Sites are numbered according to their listing in the EPA document shared with EPW.

- EPA IDs are given in the description of each pin, along with region.

Mountain Home Air Force Base

Chanute Air Force Base

US Savanna Army Depot Activity

Fort Riley

Plating, Inc.

Louisiana Army Ammunition Plant

South Weymouth Naval Air Station

Otis Air National Guard Base

Naval Weapons Industrial Reserve Plant

Fort Devens

Hanscom Field/Air Force Base

Silresim Chemical Corp.

W. R. Grace & Co. (Acton Plant)

Baird and McQuire

Walton & Lonsbury

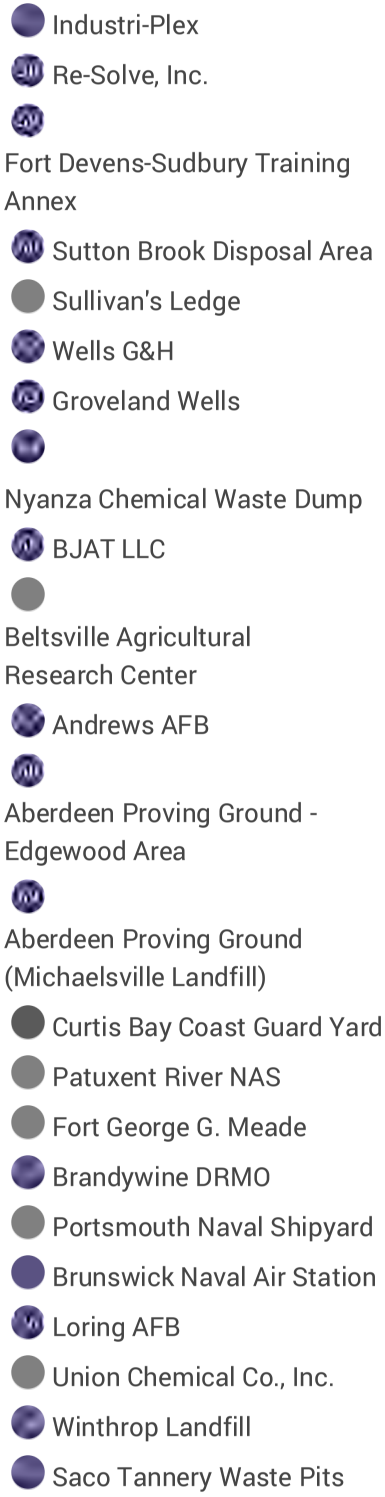
Olin Chemical

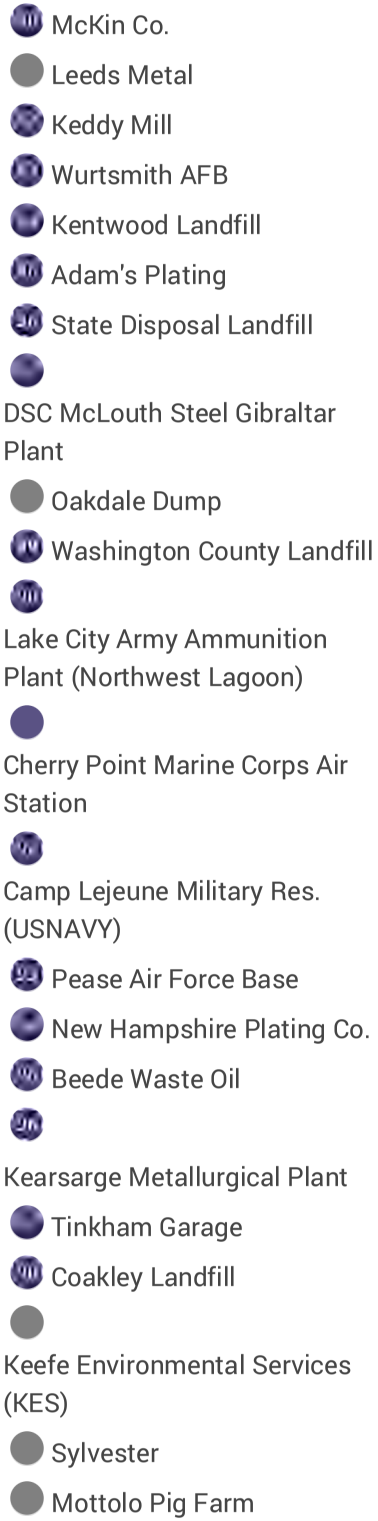
MicroFab Inc (Former)

Charles George Reclamation Trust Landfill

Iron Horse Park

Nuclear Metals, Inc.




McKin Co.
Leeds Metal
Keddy Mill
Wurtsmith AFB
Kentwood Landfill
Adam's Plating
State Disposal Landfill
DSC McLouth Steel Gibraltar Plant
Oakdale Dump
Washington County Landfill
Lake City Army Ammunition Plant (Northwest Lagoon)
Cherry Point Marine Corps Air Station
Camp Lejeune Military Res. (USNAVY)
Pease Air Force Base
New Hampshire Plating Co.
Beede Waste Oil
Kearsarge Metallurgical Plant
Tinkham Garage
Coakley Landfill
Keefe Environmental Services (KES)
Sylvester
Mottolo Pig Farm

Dover Municipal Landfill

Troy Mills Landfill

Somersworth Sanitary Landfill

Auburn Road Landfill

Savage Municipal Water Supply

South Municipal Water Supply Well

Tibbetts Road

Ottati & Goss/Kingston Steel Drum

Collins & Aikman Plant (former)

Naval Weapons Station Earle (Site A)

McGuire Air Force Base #1

Fort Dix (landfill site)

Picatinny Arsenal

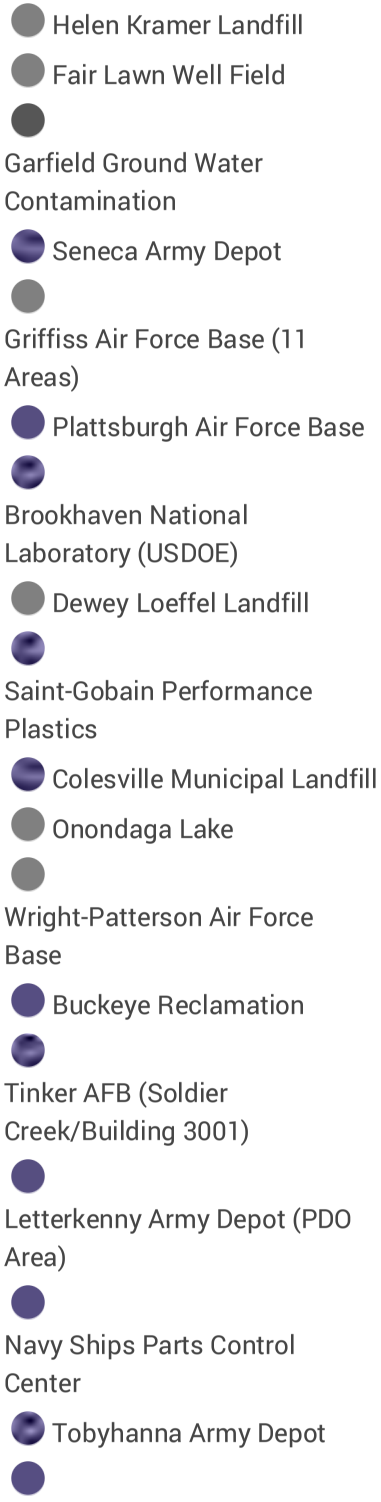
Naval Air Engineering Center

Federal Aviation Administration Technical Center (USDOT)

Orange Valley Regional Ground Water Contamination

American Cyamid Co

Martin Aaron, Inc.


Helen Kramer Landfill
Fair Lawn Well Field
Garfield Ground Water Contamination
Seneca Army Depot
Griffiss Air Force Base (11 Areas)
Plattsburgh Air Force Base
Brookhaven National Laboratory (USDOE)
Dewey Loeffel Landfill
Saint-Gobain Performance Plastics
Colesville Municipal Landfill
Onondaga Lake
Wright-Patterson Air Force Base
Buckeye Reclamation
Tinker AFB (Soldier Creek/Building 3001)
Letterkenny Army Depot (PDO Area)
Navy Ships Parts Control Center
Tobyhanna Army Depot

Naval Air Warfare Center Warminster

Letterkenny Army Depot (SE AREA)

Chem-Fab

North Penn - Area 2

AVCO Lycoming (WIlliamsport Division)

Raymark

Middletown Air Field

North Penn - Area 5

Watson Johnson Landfill

Rodale Manufacturing Co., Inc.

Valmont TCE Site (Former - Valmont Industrial Park)

WIllow Grove Naval Air and Air Reserve Station

Safety Light Corporation

Newport Naval Education & Training Center

Western Sand & Gravel

Landfill & Resource Recovery, Inc. (L&RR)

Picillo Farm

Parris Island Marine Corps Recruit Depot


Ellsworth Air Force Base


Air Force #4 (General Dynamics)


Norfolk Naval Shipyard


Langley Air Force Base/NASA Langley Research Center


Naval Air Station, Whidbey Island (AULT Field)


Fort Lewis Logistics Center


McChord Air Force Base (Wash rack/treatment area)


Fairchild Air Force Base (4 Waste Areas)


Moses Lake Wellfield Contamination


Allegany Ballistics Laboratory


F. E. Warren Air Force Base


BFI Sanitary Landfill (Rockingham)


US Defense General Supply Center (DLA)


St. Juliens Creek Annex (U.S. Navy)

Norfolk Naval Base (Sewells Point Naval Complex)

Fort Eustis (US Army)

Naval Surface Warfare Center - Dahlgren

Naval Weapons Station - Yorktown

Arrowhead Associates, Inc./Scovill Corp.

Old Springfield Landfill

Burgess Brothers Landfill

Pownal Tannery

Commerce Street Plume

Bennington Municipal Sanitary Landfill

Davisville Naval Construction Battalion

MCAS El Toro

EXHIBIT

C-136

Congress of the United States
Washington, DC 20515

May 26, 2020

The Honorable Adam Smith
Chairman
House Armed Services Committee
2216 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Mac Thornberry
Ranking Member
House Armed Services Committee
2216 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Smith and Ranking Member Thornberry:

As you begin crafting the Fiscal Year (FY) 2021 National Defense Authorization Act (NDAA), we write to express our strong support for the inclusion of necessary and comprehensive clean-up provisions to address harmful per- and polyfluoroalkyl substances (PFAS) that continues to contaminate military bases, surrounding communities, and our environment and drinking water nationwide.

We thank you for your leadership and your efforts to include PFAS specific provisions in the FY2020 NDAA, but significant and decisive action is still needed.

Since the enactment of last year's defense authorization, the number of confirmed PFAS contamination sites at active or closed military instillations has increased from 401 to 651 nationwide according to a new assessment from the Department of Defense (DOD).[1] The Environmental Working Group has also separately identified 328 military sites with known PFAS contamination, as of April 2020.[2]

The House took bold, bipartisan action in January to meet the PFAS contamination crisis head-on by passing H.R. 535, the PFAS Action Act, in a 247-159 vote. The vote included a strong showing of support from 24 Republican members representing districts in Michigan, California, Washington, Texas, Florida, New York, North Carolina, West Virginia, New Jersey, Arkansas, Nebraska, Wisconsin, and Ohio.

The PFAS Action Act is a landmark bill that includes a comprehensive package of provisions led by many of our House colleagues and assembled through regular order in the Energy and Commerce Committee. And we continue to collectively work hard to advance and enact this important bill. Among the many good provisions, the foundation of this bill is aimed at accelerating PFAS contamination clean-up for the most harmful chemicals and limiting human

[1] Department of Defense. (2019). *Per- and Polyfluoroalkyl Substances (PFAS) Task Force Progress Report March 2020*. P. 6. Retrieved from https://media.defense.gov/2020/Mar/13/2002264440/-1/-1/1/PFAS_Task_Force_Progress_Report_March_2020.pdf

[2] Environmental Working Group. (April 2020). *Interactive Map: Military Sites with Known and Suspected Discharges of PFAS*. Retrieved from https://www.ewg.org/interactive-maps/2019-pfas-crash-training-military-sites-March2020/map/

exposure to PFAS by establishing a national drinking water standard and by limiting industrial PFAS emissions and pollution into the air, water, and soil.

In particular, the PFAS Action Act would require the U.S. Environmental Protection Agency (EPA) to list PFOA and PFOS as hazardous substances under Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, or Superfund Program), and to determine whether to list other PFAS as hazardous substances within five years. In addition to PFOA and PFOS, PFHxS, PFHpA, PFHxA, PFDA, and PFNA are commonly found at DOD installations and pose many of the same health risks. The highest detection recorded at a DOD installation is for PFHxS—not PFOA and PFOS—and studies suggest that PFHxS causes liver damage, reduces the effectiveness of vaccines, and increases the risk of early menopause and osteoporosis. PFHxS, PFBS, PFHxA, and PFNA have all been subject to specific state limitations, and PFHpA and PFDA have included into the "Sum of PFAS" maximum contaminant levels (MCLs) set by two states.

We urge you and every member of the House Armed Services Committee take this crisis seriously and ensure strong provisions on PFAS clean-up are included in any final FY2021 National Defense Authorization Act. Thank you for all that you do each year to keep our nation's defenses strong to safeguard the American people and care for our servicemembers and their families in all branches of the U.S. Armed Forces.

Your attention to this important matter is appreciated and we stand ready to work with you throughout this process to find bipartisan solutions to the critical human health and environmental challenges PFAS contamination poses to us all.

Sincerely,

Debbie Dingell
Member of Congress

Ann McLane Kuster
Member of Congress

Chris Pappas
Member of Congress

Lisa Blunt Rochester
Member of Congress

Call for Strong PFAS Clean-up Provisions in FY2021 NDAA
List of Signatories
May 26, 2020

Gregorio Kilili Camacho Sablan
Gwen Moore
Brian Fitzpatrick
Madeleine Dean
Eleanor Holmes Norton
Ro Khanna
Joe Neguse
Steve Cohen
Bobby L. Rush
Pramila Jayapal
Tom Malinowski
Nanette Diaz Barragán
Nydia M. Velázquez
Jamie Raskin
Bill Foster
Barbara Lee
Bonnie Watson Coleman
Henry C. "Hank" Johnson, Jr.
Earl Blumenauer
Kathy Castor
Elaine G. Luria
Sean Patrick Maloney
Richard E. Neal
Tony Cárdenas
Denny Heck
Sheila Jackson Lee
Bennie G. Thompson
Debbie Wasserman Schultz
Rashida Tlaib
Harley Rouda
Debbie Mucarsel-Powell
Raúl M. Grijalva
Linda T. Sánchez
Alan Lowenthal
Thomas R. Suozzi
Adriano Espaillat

Gerald E. Connolly
Sean Casten
Katie Porter
Peter Welch
A. Donald McEachin
Scott Peters
James P. McGovern
Mary Gay Scanlon
Julia Brownley
Anna G. Eshoo
Katherine Clark
Darren Soto
Antonio Delgado
John P. Sarbanes
Jerry McNerney
Matthew Cartwright
Jan Schakowsky
Paul D. Tonko
Josh Gottheimer
John Yarmuth
Robert C. "Bobby" Scott
Ben Ray Luján
Daniel T. Kildee
Peter A. DeFazio
David Trone
David Cicilline
Mikie Sherrill
TJ Cox
Elissa Slotkin
Haley M. Stevens
Brian Higgins
Alcee L. Hastings
Mike Thompson
Jesús G. "Chuy" García
Tulsi Gabbard
André Carson
Derek Kilmer
Josh Harder
Kathleen M. Rice

Grace F. Napolitano
Mike Quigley
Andy Levin
Brenda L. Lawrence
Albio Sires
Raja Krishnamoorthi
Suzanne Bonamici
Joseph P. Kennedy, III
Judy Chu
Bill Posey
Jared Huffman
Tim Ryan
Joseph D. Morelle
David Price
Betty McCollum
Sheila Jackson Lee
Deb Haaland
Juan Vargas
Chellie Pingree
Peter T. King
Fred Upton
David Rouzer
Donald M. Payne, Jr.
Ann Kirkpatrick
Donald S. Beyer Jr.
Alma S. Adams, Ph.D.
Lucille Roybal-Allard
Jahana Hayes
Marcy Kaptur
Alexandria Ocasio-Cortez
Gregory W. Meeks
Eddie Bernice Johnson
C.A. Dutch Ruppersberger
Susan Wild
Mark Pocan
Grace Meng
Ted Lieu

EXHIBIT

C-137

Attorneys General of the States of California, Colorado, Connecticut, Delaware, District of Colombia, Illinois, Iowa, Maine, Maryland, Massachusetts, Minnesota, Nevada, New Jersey, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Virginia, Washington, and Wisconsin

June 10, 2020

Via Regulations.gov
Water Docket
Environmental Protection Agency
Mail Code: [28221T]
1200 Pennsylvania Ave. NW
Washington, D.C. 20460

Re: Comments on *Preliminary Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List*, 85 Fed. Reg. 14098 (Mar. 10, 2020)

Docket ID No. EPA-HQ-OW-2019-0583

Dear Administrator Wheeler:

The state attorneys general of California, Colorado, Connecticut, Delaware, District of Colombia, Illinois, Iowa, Maine, Maryland, Massachusetts, Minnesota, Nevada, New Jersey, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Virginia, Washington, and Wisconsin (collectively, the States) appreciate the opportunity to offer comments on the Environmental Protection Agency's (EPA) *Preliminary Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List* (Preliminary Determination), 85 Fed. Reg. 14098 (Mar. 10, 2020). In the Preliminary Determination, EPA announces its decision to regulate perfluorooctanesulfonic acid (PFOS) and perfluorooctanoic acid (PFOA),[1] chemicals which belong to a large class of per- and polyfluoroalkyl substances (PFAS).[2] 85 Fed.

[1] Preliminary Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List (Preliminary Determination), 85 Fed. Reg. 14,098, 14,120 (Mar. 10, 2020). These comments address only EPA's decision to regulate PFOA and PFOS and do not address EPA's announced decisions not to regulate the six other non-PFAS contaminants EPA is considering for regulation here.

[2] PFAS are a subset of fluorochemicals, which are highly fluorinated aliphatic substances that "contain 1 or more C atoms on which all the H substituents…have been replaced by F atoms, in such a manner that they contain the perfluoroalkyl moiety," denoted by the chemical formula $R–C_nF_{2n+1}$. N is an integer greater than zero and the "R–" represents a bond between a functional group (e.g. carboxylic acid or sulfonic acid) and the

Reg. 14120. EPA's preliminary determination is the first step toward the development of a National Primary Drinking Water Regulation (NPDWR) and a maximum contaminant level (MCL) for PFOA and PFOS pursuant to the federal Safe Drinking Water Act (SDWA).[3]

As stated in the Preliminary Determination, "PFAS are a group of synthetic chemicals that have been in use since the 1940s" and "are found in a wide array of consumer and industrial products."[4] PFOA and PFOS are "two of the most widely-studied and longest-used PFAS."[5] In addition to direct human exposure to PFAS through the use of consumer and industrial products, "PFAS manufacturing and processing facilities, facilities using PFAS in production of other products, airports, and military installations have been associated with PFAS releases into the air, soil, and water."[6] As part of a nationwide health study, the Centers for Disease Control and Prevention has been testing for various PFAS, including PFOA and PFOS, in the blood of adults and children since 1999, finding that "most people in the United States have one or more specific PFAS in their blood."[7] Elevated levels of PFOA and PFOS have also been detected in public water systems serving millions of people across the United States.[8]

The States have a significant interest in ensuring that their residents have access to safe drinking water. Although PFAS have been shown to negatively affect human health, there is currently no national requirement that all public water systems test for and remove unsafe levels of PFAS in drinking water.[9] Considering that millions of people across the United States rely on public drinking water systems contaminated with PFAS, and the limited resources available to states to comprehensively address PFAS, EPA should regulate PFAS, including PFOA and PFOS, under the SDWA to set nationwide baseline drinking water standards and to protect public health.

---

perfluoroalkyl tail. *See* Buck et al. 2011. *Perfluoroalkyl and polyfluoroalkyl substances in the environment: terminology, classification, and origins*, Integrated Envtl. Assessment and Mgmt. 7 (4), 513–541 (2011), https://www.ncbi.nlm.nih.gov/pubmed/21793199. The term PFAS includes all known perfluoroalkyl substances and all known polyfluoroalkyl substances, regardless of chain length, as well as potentially created perfluoroalkyl substances and polyfluoroalkyl substances.

[3] Preliminary Determination at 14,110.

[4] *Id.* at 14,115.

[5] *Id.*

[6] *Id.*

[7] *PFAS Blood Testing*, Agency for Toxic Substances and Disease Registry, https://www.atsdr.cdc.gov/pfas/pfas-blood-testing.html (last visited Apr. 9, 2020). *See also* 85 Fed. Reg. 14115 (PFOS and PFOA "have been detected in up to 98% of serum samples taken in biomonitoring studies that are representative of the U.S. general population").

[8] Preliminary Determination, 85 Fed. Reg. at 14,117–18.

[9] *Id.* at 14,115–17.

Set forth below are the States' comments responding to EPA's preliminary determination to regulate PFOS and PFOA under the SDWA.[10] First, the States support EPA's Preliminary Determination to set NPDWRs for PFOA and PFOS and agree that these contaminants meet the three statutory criteria set forth in SDWA section 1412(b)(1)(A), 42 U.S.C. § 300g-1(a)(1). Second, the States urge EPA to propose final NPDWRs for PFOA and PFOS that are well below EPA's existing Health Advisory Level in order to reflect current science and protect human health. Third, we encourage EPA to regulate other PFAS in addition to PFOA and PFOS, and to evaluate potential approaches to regulate PFAS as a class. Fourth, we encourage EPA to promulgate final NPDWRs as soon as possible to protect public health, but no later than 18 months from the time the final determination to regulate is made.

A. EPA's Preliminary Determination to regulate PFOA and PFOS under the Safe Drinking Water Act is appropriate and necessary to protect public health.

The States agree with and support EPA's Preliminary Determination that PFAS, specifically PFOA and PFOS, meet the statutory criteria to regulate under section 1412(b)(1)(A) of the SDWA; namely, (1) the chemicals "may have an adverse effect on the health of persons," (2) the chemicals are "known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern," and (3) regulating these chemicals "presents a meaningful opportunity for health risk reduction for persons served by public water systems."[11] Because other PFAS, as well as PFAS as a class, also meet the statutory criteria, as discussed in Section C below, we urge EPA to regulate other PFAS, as well as to evaluate approaches to regulate the entire PFAS class, under section 1412(b)(1)(A).

1. Exposure to PFOA and PFOS has an adverse effect on human health.

We agree with EPA that substantial scientific evidence demonstrates that PFOA and PFOS have adverse effects on human health and meet the first statutory criterion for regulation under the SDWA. The toxicity of PFOA and PFOS to humans and animals has been studied for decades, including internal tests conducted by 3M on PFOS and by DuPont on PFOA.[12] As recited in the Preliminary Determination, the vast body of research demonstrates serious adverse health

[10] *Id.* at 14,107.
[11] 42 U.S.C. § 300g-1(a)(1).
[12] *See, e.g.,* Office of Minn. Attorney General Keith Ellison, *State's Second Amended Exhibit List*, https://www.ag.state.mn.us/Office/Cases/3M/StatesExhibits.asp (last visited Apr. 15, 2020) (providing documentation of, *inter alia*, research performed by 3M and DuPont regarding the toxic effects of PFOA and PFOS exposure to humans and animals).

effects associated with exposure to PFOA and PFOS, including "decreases in female fecundity and fertility, decreased birth weights in offspring and other measures of postnatal growth," as well as "high cholesterol, increased liver enzymes, decreased vaccination response, thyroid disorders, pregnancy-induced hypertension and preeclampsia, and cancer."[13]

However, PFOA and PFOS are not the only chemicals within the PFAS class that present health risks to humans. Due to characteristics shared by all PFAS, other PFAS show similar indicia of toxicity, environmental persistence, bio-accumulation, and ubiquity in the environment.[14] Additionally, many members of the PFAS class are chemical precursors known to break down or transform into PFOA and PFOS in the environment and the human body.[15] These types of PFAS pose similar health risks as PFOA and PFOS.[16] Moreover, precursor PFAS may pose increased toxicity compared to their break down or transformation products. For example, one of the precursors to perfluorohexanoic acid (PFHxA) has been shown to be significantly more toxic than PFHxA.[17]

In the Preliminary Determination, EPA relies on the Health Effects Support Documents (HESDs) that it published in 2016 to aid in its development of Health Advisory Levels for PFOA and PFOS. These documents synthesize decades of

---

[13] Preliminary Determination, 85 Fed. Reg. at 14,115–16; *see also* Agency for Toxic Substances & Disease Registry, U.S. Dep't of Health & Human Servs., *What are the health effects?*, https://www.atsdr.cdc.gov/pfas/health-effects.html (last visited Jan. 21, 2020) (reporting that human exposure to PFAS, such as PFOA and PFOS, may increase the risk of cancer, alter the immune system, increase cholesterol levels, interfere with natural hormones, decrease fertility, and affect the growth, learning, and behavior of infants and children); Cal. Water Bds., *Per- and Polyfluoroalkyl Substances (PFAS)*, https://www.waterboards.ca.gov/pfas (last updated Apr. 9, 2020) (human exposure to PFAS, such as PFOA and PFOS, may also result in low birth weight, birth defects, delayed puberty onset, increased risk of thyroid disease, and increased risk of asthma).

[14] Attorneys General of New York et al., Comment Letter on the Advance Notice of Proposed Rulemaking, Addition of Certain Per- and Polyfluoroalkyl Substances; Community Right-to-Know Toxic Chemical Release Reporting (Feb. 3, 2020), https://www.regulations.gov/document?D=EPA-HQ-TRI-2019-0375-0086.

[15] Buck et al., *supra* at 513–541; Concawe, *Environmental Fate and Effects of Poly- and Perfluoroalkyl Substances (PFAS)*, Report No. 8/16 - Environmental Science for the European Refining Industry (2016), https://www.concawe.eu/wp-content/uploads/2016/06/Rpt_16-8.pdf.

[16] Buck et al., *supra* at 513–541; Concawe, *supra* note 15; Attorneys General Comment Letter, *supra* note 14.

[17] Rice et al., *Comparative analysis of the toxicological databases for 6:2 fluorotelomer alcohol (6:2 FTOH) and perfluorohexanoic acid (PFHxA)*, 138 FOOD CHEM TOXICOL. 111210 (Apr. 2020), https://www.sciencedirect.com/science/article/pii/S0278691520300983?via%3Dihub.

animal and human studies demonstrating that PFOA and PFOS are toxic at very low concentrations. Based, in part, on these HESDs, EPA derived a health reference level for the combined concentration of PFOA and PFOS of 70 parts per trillion (ppt). For the Preliminary Determination, EPA uses this health reference level to evaluate the occurrence of the contaminants in public water systems.[18]

Recent analyses indicate that to adequately protect public health, the health reference level for this determination should be lower than EPA's Health Advisory Level.[19] In 2018, the Agency for Toxic Substances Disease Registry (ATSDR) developed draft minimal risk levels for PFOA and PFOS as a screening tool to identify exposures that could potentially be hazardous to human health.[20] ATSDR's draft minimal risk levels are significantly lower than the reference doses that EPA used to generate its Health Advisory Level.[21] Similarly, the New Jersey Drinking Water Quality Institute (NJDWQI) evaluated the basis of the EPA Health Advisories for PFOA in 2017[22] and PFOS in 2018[23] and concluded that "elevations in serum PFOA levels of the magnitude expected from ongoing exposure to 70 ng/L (the USEPA Health Advisory) in drinking water are not desirable and may not be protective of public health." The NJDWQI concluded that EPA's "reasons for dismissing low-dose toxicological effects [of PFOA] do not appear to be scientifically valid and/or are also equally or more applicable to the endpoints selected by EPA,"[24]

---

[18] Preliminary Determination, 85 Fed. Reg. at 14,115–17.

[19] *See infra* part III.B.

[20] Agency for Toxic Substances & Disease Registry, U.S. Dep't of Health & Human Servs., *PFAs Toxicological Profile Key messages* (June 2018), https://www.atsdr.cdc.gov/docs/PFAS_Public_KeyMessages_June20_Final-508.pdf.

[21] Agency for Toxic Substances & Disease Registry, U.S. Dep't of Health & Human Servs., *Toxicological Profile for Perfluoroalkyls: Draft for Public Comment* (June 2018),https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf; *see also infra* part B.

[22] N.J. Drinking Water Quality Institute Health Effects Subcommittee, *Health-based Maximum Contaminant Level Support Document: Perfluorooctanoic Acid (PFOA)*, Appendix 2: Comparison of USEPA Office of Water Health Advisory and DWQI recommended Health-based MCL for PFOA (Feb. 15, 2017), https://www.state.nj.us/dep/watersupply/pdf/pfoa-appendixa.pdf.

[23] N.J. Drinking Water Quality Institute Health Effects Subcommittee, *Health-based Maximum Contaminant Level Support Document: Perfluorooctane Sulfonate (PFOS)*, Appendix 2: Comparison of USEPA Office of Water Health Advisory and DWQI Health-based MCL for PFOS (June 5, 2018), https://www.state.nj.us/dep/watersupply/pdf/pfos-recommendation-appendix-a.pdf.

[24] N.J. Drinking Water Quality Institute Health Effects Subcommittee, *Health-based Maximum Contaminant Level Support Document: Perfluorooctanoic Acid (PFOA)*, Appendix 2: Comparison of USEPA Office of Water Health Advisory and DWQI recommended Health-based MCL for PFOA (Feb. 15, 2017), https://www.state.nj.us/dep/watersupply/pdf/pfoa-appendixa.pdf.

and that EPA "dismissed the most sensitive toxicological effect in animal studies . . . from consideration as the basis for [PFOS] risk assessment."[25] Furthermore, in 2018, the Michigan PFAS Science Advisory Panel analyzed toxicology and epidemiology studies and concluded that long-term exposure to drinking water containing concentrations of PFOA below 70 ppt could result in adverse health effects.[26] Thus, the evidence underlying EPA's Preliminary Determination and more recent scientific analyses, which are discussed in more detail below, demonstrate that PFOA and PFOS, and other chemicals in the PFAS class, have an adverse effect on human health, even at concentrations far below EPA's Health Advisory Level.

2. PFOA and PFOS are found in public water systems with a frequency and at levels of public health concern.

The States agree with EPA's Preliminary Determination that PFOA and PFOS meet the second statutory criterion for regulation under the SDWA because they occur in public water systems with a frequency and at levels of public health concern. This determination is supported by the Unregulated Contaminant Monitoring Rule (UCMR) 3 data, state data gathered by EPA, and the additional data provided in these comments.

In the Preliminary Determination, EPA determined that the UCMR 3 data, which were collected from 2013 to 2015, represents the best available occurrence information for PFOA and PFOS.[27] The UCMR 3 occurrence data show that one or more PFAS were detected in 4 percent of reporting public water systems.[28] We agree that these data demonstrate that PFOA and PFOS occur in public water systems at a frequency of public health concern.

However, the UCMR 3 data underrepresent the occurrence of PFOA and PFOS in public water systems. As the UCMR 3 data focus on public water systems serving more than 10,000 customers, it excludes many smaller public water systems which are close to PFAS sources and vulnerable to PFAS contamination. Furthermore, the UCMR 3 survey used a minimum reporting level of 20 ppt for

---

[25] N.J. Drinking Water Quality Institute Health Effects Subcommittee, *supra* note 21, App'x 2.

[26] Mich. PFAS Science Advisory Panel, *Scientific Evidence and Recommendations for Managing PFAS Contamination in Michigan* (Dec. 7, 2018), https://www.michigan.gov/documents/pfasresponse/Science_Advisory_Board_Report_641294_7.pdf.

[27] Preliminary Determination, 85 Fed. Reg. at 14,117.

[28] Interstate Tech. & Regulatory Council, *Environmental Fate and Transport for Per- and Polyfluoroalkyl Substances* 12 (Apr. 2020), https://pfas-1.itrcweb.org/fact_sheets_page/PFASFact_Sheet_Fate_and_Transport_April2020.pdf.

PFOA[29] and 40 ppt for PFOS.[30] Several states and ATSDR have concluded that contamination below these levels are harmful to human health but lower levels of contamination were not reported in the UCMR 3 data. More recent state sampling conducted with much lower minimum reporting levels has detected more widespread PFAS contamination than the UCMR 3 data.[31] Additionally, PFAS were detected much more frequently than was reported in UCMR 3 data when a large subset of the UCMR 3 PFAS analytical results were reevaluated using lower reporting levels by a laboratory that analyzed about 30% of all UCMR 3 PFAS samples.[32]

The States also present data regarding the occurrence of PFOA and PFOS, as well as other PFAS chemicals, in public water systems and in surface water and groundwater.[33] For example, the following data support EPA's determination that PFAS occur in our waters with a frequency and at levels of public health concern:

- At Joint Base Lewis-McChord in Washington, the Army sampled 4 drinking water supply wells, all of which had combined PFOA and PFOS over EPA's Health Advisory Level of 70 ppt, ranging from 72 to 250 ppt.[34]

---

[29] U.S. Envtl. Prot. Agency, *Regulatory Determination 4 Support Document* 4-16 (Dec. 2019), https://www.regulations.gov/document?D=EPA-HQ-OW-2019-0583-0004.

[30] *Id.* at 3-15. Minimum reporting levels for other PFAS may also underrepresent the occurrence of these PFAS at concentrations of public health concern. For example, UCMR 3 minimum reporting levels are 90 ppt for perfluorobutanesulfonic acid (PFBS), 10 ppt for perfluoroheptanoic acid (PFHpA), 30 ppt for perfluorohexanesulfonic acid (PFHxS), and 20 ppt for perfluorononanoic acid (PFNA). U.S. Envtl. Prot. Agency, *Third Unregulated Contaminant Monitoring Rule (UCMR 3): Data Summary* (Jan. 2017), https://www.epa.gov/sites/production/files/2017-02/documents/ucmr3-data-summary-january-2017.pdf.

[31] *Regulatory Determination 4 Support Document* at 3-20-22, 3-22-24, 4-21-23, 4-24-25.

[32] Post, Gloria B. et. al, *Key scientific issues in developing drinking water guidelines for perfluoroalkyl acids: Contaminants of emerging concern*, PLOS BIOL. 15(12) (Dec. 20, 2017), https://journals.plos.org/plosbiology/article/file?id=10.1371/journal.pbio.2002855&type=printable.

[33] In addition to the UCMR 3 data, EPA evaluated other sources of finished drinking and ambient water occurrence data. Preliminary Determination, 85 Fed. Reg. at 14,111-13. For additional information about the occurrence of PFAS throughout the country, see the interactive map created by the Environmental Working Group at https://www.ewg.org/aboutpfasmap.

[34] Maureen Sullivan, *Addressing Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA)* (Mar. 2018), https://partner-mco-archive.s3.amazonaws.com/client_files/1524589484.pdf.

- At Letterkenny Army Depot in Pennsylvania, the Army sampled 24 groundwater monitoring wells, 6 of which had combined PFOA and PFOS concentrations between 82 and 2,069 ppt.[35]
- At Seneca Army Ammunition Plant in New York, the Army sampled 43 groundwater monitoring wells, 16 of which had combined PFOA and PFOS concentrations that ranged from 580 to 89,000 ppt.[36]
- At Warminster Naval Base in Pennsylvania, 4 of 17 nearby public water supply wells sampled by the Navy had combined PFOA and PFOS concentrations between 88 and 1,300 ppt.[37]
- At the China Lake Naval Air Weapons Station in California, the Navy tested 11 wells, 7 of which had combined PFOA and PFOS concentrations between 3,800 and 8,000,000 ppt.[38]
- At Fort McCoy in Wisconsin, the Army tested 27 groundwater monitoring wells, 14 of which had PFAS concentrations that ranged from 70 to 120,000 ppt.[39]
- In the City of La Crosse, Wisconsin, concentrations of PFOA and PFOS in one municipal well have been observed as high as 22.3 ppt for PFOA and 188 ppt of PFOS.[40]
- In the City of Madison, Wisconsin, surface water[41] samples downstream of a known source of PFAS, Truax Field Air National Guard Base, showed 360 ppt of PFOS, 43 ppt of PFOA.[42]
- In the cities of Marinette and Peshtigo, Wisconsin, a site investigation revealed that out of 168 drinking water wells

---

[35] *Id.*
[36] *Id.*
[37] *Id.*
[38] *Id.*
[39] *Id.*
[40] Wis. Dep't of Nat. Res., *Summary of Results from Sampling Program at Well 23*, https://dnr.wi.gov/botw/GetActivityDetail.do?adn=0232000065&siteId=4221400&crumb=1&search=a (follow "20190418_43_monitoring_Qtrly_April_2019.pdf" hyperlink) (last visited Apr. 15, 2020).
[41] The surface water, Starkweather Creek, is hydrologically connected to groundwater that is used as the City of Madison's drinking water source. Nelson Institute for Environmental Studies at the University of Wisconsin – Madison, *Starkweather Creek Watershed: Current Conditions and Improvement Strategies*, WATER RESOURCES PRACTICUM 2005 (2006), https://www.nelson.wisc.edu/docs/report.pdf.
[42] Wis. Dep't of Nat. Res., *2019 PFAS Surface Water Sampling Results*, https://dnr.wi.gov/topic/Contaminants/documents/pfas/SurfaceWaterReport20191015.pdf (last visited Apr. 15, 2020).

sampled, 16 had combined PFOA and PFOS concentrations above EPA's Health Advisory Level, and 29 had combined PFOA and PFOS concentrations above 20 ppt.[43]

- In February of 2018, PFOA and PFOS were found in three public wells maintained by the Town of Blades, in southern Delaware. The combined PFOA and PFOS concentration in the wells ranged from 96.2 to 187.1 ppt. The municipal water system servicing 1200 people was shut down, until a carbon filtration system could be installed. The suspected source of the contamination was a defunct metal plating company.[44]
- For many years, DuPont (now Chemours) operated an industrial facility known as the Chambers Works in Deepwater, New Jersey on the Delaware River, which discharged wastewater into the tidal waters of the River.[45] Tests conducted by the Delaware River Basin Commission have found excessive concentrations of PFAS in the River and Bay estuary.[46]

Thus, the occurrence data in EPA's Preliminary Determination and the additional data provided in this comment demonstrate that PFOA and PFOS occur in public water systems, in surface water, and in groundwater with a frequency and at levels of public health concern. However, due to EPA's use of a health reference level of 70 ppt to evaluate the occurrence data, the EPA's occurrence data in the UCMR 3 survey may significantly underrepresent the actual occurrence of PFOA and PFOS at levels of human health concern.

3. <u>The regulation of PFOA and PFOS presents a meaningful opportunity to reduce the health risk for persons who use public water systems</u>.

The States support EPA's conclusion that the regulation of PFOA and PFOS presents a meaningful opportunity for health risk reduction. In the Preliminary Determination, EPA recognizes significant public concern regarding these contaminants and public interest in the promulgation and enforcement of a national

---

[43] Wisconsin Dep't of Nat. Res., PFAS contamination in the Marinette and Peshtigo area, Drinking water sampling and analysis, (revised May 22, 2020), https://dnr.wi.gov/topic/Contaminants/Marinette.html.

[44] Northwestern University Social Science Environmental Health Research Institute, Per- and Polyfluoroalkyl Substances, Blades, Delaware, https://pfasproject.com/bladesdelaware/.

[45] Northwestern University Social Science Environmental Health Research Institute, Per- and Polyfluoroalkyl Substances, Deepwater, Salem County, New Jersey, https://pfasproject.com/deepwater-salem-county-new-jersey/.

[46] Delaware River Basin Commission, *Contaminants of Emerging Concern in the Tidal Delaware River, Pilot Monitoring Survey 2001-2009*, at 33 (Aug. 2013), https://www.nj.gov/drbc/library/documents/contaminants-of-emerging-concernAug2013rev.pdf.

drinking water standard.[47] As stated throughout these comments, the States recommend that EPA regulate other PFAS, and evaluate approaches to regulate PFAS as a class, which presents a more comprehensive and meaningful opportunity to reduce the health risks for persons who use public water systems.

While some states have developed and others are in the process of developing their own PFAS drinking water standards, many states do not have the capacity or resources to do so.[48] Without a federal NPDWR and MCL for PFAS, public water systems in many states will not be required to monitor or address PFAS contamination. Thus, if EPA does not adopt appropriate protective federal drinking water standards, residents of states that have not regulated or otherwise addressed PFAS contamination may continue to be exposed to harmful levels of these chemicals.

Regulating PFOA and PFOS contamination in drinking water presents a meaningful opportunity for health risk reduction because enforceable, health-based, standards that are sufficiently stringent will protect the public, including sensitive populations such as newborns, infants, and children. Reducing health risks is especially critical in areas where PFOA and PFOS occur in public water systems at levels harmful to human health. Because PFOA and PFOS are highly persistent in the environment, have high mobility, and can form as a result of precursor transformations, the need to reduce PFOA and PFOS contamination in public water systems will continue even as the production, use, and disposal of PFAS become more regulated or phased out.[49] The state data summarized in these comments confirm that many public water systems are contaminated with PFOA and PFOS at concentrations that exceed EPA's Health Advisory Level of 70 ppt by several orders of magnitude.

B. Experts link adverse health impacts to exposure to PFOA and PFOS at levels lower than EPA's current Health Advisory Level.

In the four years since EPA set the Health Advisory Level for PFOA and PFOS at 70 ppt, additional scientific research and further analysis of existing research have continued to improve our understanding of how PFAS affect the human body. As more is learned about these contaminants, it becomes increasingly

---

[47] Preliminary Determination, 85 Fed. Reg. at 14,119.

[48] Envt'l Council of the States, *Processes & Considerations for Setting State PFAS Standards* 7 (Feb. 2020), https://www.ecos.org/wp-content/uploads/2020/02/Standards-White-Paper-FINAL-February-2020.pdf.

[49] Concawe, *Environmental Fate and Effects of Poly- and Perfluoroalkyl Substances (PFAS)*, Report No. 8/16 - Environmental Science for the European Refining Industry (2016), https://www.concawe.eu/wp-content/uploads/2016/06/Rpt_16-8.pdf.

apparent that exposure to PFOA and PFOS is linked to adverse health effects in humans even at concentrations that are far lower than the current Health Advisory Level.[50] It is critical that EPA incorporate new scientific information and analyses into its regulatory development process to ensure its drinking water standards are adequately protective of human health.[51]

Evolving human epidemiology and animal toxicology data, concerns over the environmental mobility and persistence of PFAS, and widespread human exposure and environmental contamination have led scientists and health professionals to conclude that EPA's Health Advisory Level far exceeds a safe level of exposure to PFOA and PFOS. In 2018, the ATSDR developed draft minimal risk levels for PFOA and PFOS. These draft minimal risk levels are lower than previous levels because ATSDR took into account more sensitive developmental effects and immune effects, which can occur at lower concentrations than developmental effects used as the basis for the EPA Health Advisory and earlier ATSDR evaluations.[52] ATSDR's analysis indicates that a lower drinking water standard is necessary, as EPA's Health Advisory Level did not account for these more sensitive developmental effects or for immune effects.[53] Additionally, the European Food Safety Authority (EFSA) recently developed a draft Tolerable Daily Intake for total exposure to

---

[50] The Pennsylvania Department of Environmental Protection (DEP) is currently in the process of evaluating drinking water standards for certain PFAS, including PFOA and PFOS. For that reason, Pennsylvania joins these comments only to the extent that they discuss the public health concerns presented by PFAS, highlight the states' interest in protecting our residents from the adverse health effects of PFAS exposure, argue for the importance of proper regulation of these chemicals by EPA, and urge EPA to move as expeditiously as possible to develop water quality standards for PFOA and PFOS. Given DEP's ongoing evaluations, Pennsylvania takes no position on specific recommendations, scientific conclusions, or the validity of any of the scientific sources referenced herein.

[51] The Colorado Department of Public Health and Environment (CDPHE) is currently in the process of evaluating the best regulatory approach to address PFAS, including PFOA and PFOS. For that reason, Colorado joins these comments only to the extent that they discuss the public health concerns presented by PFAS, highlight the states' interest in protecting our residents from the adverse health effects of PFAS exposure, argue for the importance of proper regulation of these chemicals by EPA, and urge EPA to move as expeditiously as possible to develop drinking water standards for PFOA and PFOS. Given CDPHE's ongoing evaluations, Colorado takes no position on specific recommendations, scientific conclusions, or the validity of any of the scientific sources referenced herein.

[52] Agency for Toxic Substances & Disease Registry, U.S. Dep't of Health & Human Servs., *PFAs Toxicological Profile Key messages* (June 2018), https://www.atsdr.cdc.gov/docs/PFAS_Public_KeyMessages_June20_Final-508.pdf.

[53] Agency for Toxic Substances & Disease Registry, U.S. Dep't of Health & Human Servs., *Toxicological Profile for Perfluoroalkyls: Draft for Public Comment* (June 2018), https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf.

PFOA, PFOS, and two other PFAS based on decreased response to vaccination in children exposed to PFAS in breast milk. This Tolerable Daily Intake is approximately twenty times lower than the EPA Reference Dose.[54] In addition to other reasons for setting a lower drinking water standard,[55] these analyses indicate that EPA's current Health Advisory Level does not sufficiently protect public health.

Based on developments in PFAS research and states' independent analyses, several states have developed, or are in the process of developing, drinking water and health-based groundwater standards for PFOA and PFOS that are much lower than the federal Health Advisory Level of 70 ppt. These lower state standards consider sensitive toxicological effects in laboratory animals and human health effects that EPA did not take into account when developing the Health Advisory Level of 70 ppt.[56] For a comparison of states' existing and developing PFAS standards, please refer to Appendix A.

The NJDWQI, for example, performed comparative analyses of EPA's and its own risk assessments of PFOA and PFOS. The NJDWQI determined that EPA's Health Advisory Level is not sufficiently health protective and recommended drinking water standards of 13 ppt for PFOS and 14 ppt for PFOA.[57] Subsequently,

---

[54] European Food Safety Authority, *PFAS public consultation: draft opinion explained*, https://www.efsa.europa.eu/en/news/pfas-public-consultation-draft-opinion-explained; European Food Safety Authority Panel on Contaminants in the Food Chain, Schrenk, D., *Scientific opinion on the risk for human health related to the presence of perfluoroalkyl substances in food* (draft for public comment Feb. 24, 2020), https://www.efsa.europa.eu/en/consultations/call/public-consultation-draft-scientific-opinion-risks-human-health.

[55] For instance, states may develop valid, more stringent standards based not only on the reference dose, but also on other factors. *See, e.g.,* Vt. Dep't of Health, *Drinking Water Health Advisory for Five PFAS,* at 4 (July 10, 2018), https://www.healthvermont.gov/sites/default/files/documents/pdf/ENV_DW_PFAS_HealthAdvisory.pdf (using drinking water intake rate for infant during first year of life in setting 20 ppt advisory for 5 PFAS).

[56] Post, G., *Basis of State & USEPA PFAS Drinking Water Standards & Guidelines*, PFAS Substances & Emerging Contaminants in the Environment Symposium, Air & Waste Management Association–Mid-Atlantic States Section (Jan. 22, 2020), https://www.mass-awma.net/pfas-workshop-2020-slideshows.html.

[57] N.J. Dep't of Envtl. Prot., *Affirming National Leadership Role, New Jersey Proposes Stringent Drinking Water Standards for PFOA and PFOS* (April 1, 2019), https://www.nj.gov/dep/newsrel/2019/19_0021.htm; N.J. Drinking Water Quality Institute Health Effects Subcommittee, *Health-based Maximum Contaminant Level Support Document: Perfluorooctanoic Acid (PFOA)*, (Feb. 15, 2017), https://www.state.nj.us/dep/watersupply/pdf/pfoa-appendixa.pdf; N.J. Drinking Water Quality Institute Health Effects Subcommittee, *Health-based Maximum Contaminant Level Support*

the New Jersey Department of Environmental Protection adopted MCLs and ground water quality standards of 13 ppt for PFOS and 14 ppt for PFOA.[58]

In 2019, a Michigan Science Advisory Workgroup developed Health-Based Drinking Water Value Recommendations for PFAS in Michigan.[59] Based on an examination of peer-reviewed studies, EPA's health assessment, and information provided by ATSDR, the Michigan Workgroup recommended a health-based drinking water value of 8 ppt for PFOA and 16 ppt for PFOS.[60] The Michigan Workgroup also noted that state and federal drinking water standards for PFOA and PFOS have decreased over time due to "the evolving science, both the ever-increasing knowledge gained from published toxicology and epidemiology studies and the risk assessments for development of toxicity values and drinking water values."[61]

On December 27, 2019, the Massachusetts Department of Environmental Protection published proposed revisions to the state's drinking water regulations, commencing the Commonwealth's formal process to revise the state's drinking water standards for PFAS.[62] The proposed regulation establishes a total combined MCL of 20 ppt for six PFAS, including PFOA and PFOS.[63]

Document: Perfluorooctane Sulfonate (PFOS), (June 5, 2018), https://www.state.nj.us/dep/watersupply/pdf/pfos-recommendation-appendix-a.pdf.

[58] Envt'l Council of the States, *New Jersey Sets Stringent Limits for PFOA, PFOS in Drinking Water* (Apr. 17, 2020), https://www.ecos.org/news-and-updates/new-jersey-enacts-stringent-limits-for-pfoa-pfos-in-drinking-water/; N.J. Dep't of Envtl. Prot., *Affirming National Leadership Role, New Jersey Publishes Formal Stringent Drinking Water Standards for PFOA and PFOS,* (June 1, 2020), https://www.nj.gov/dep/newsrel/2020/20_0025.htm.

[59] Mich. Sci. Advisory Workgroup, *Health-Based Drinking Water Value Recommendations for PFAS in Michigan* (2019), https://www.michigan.gov/documents/pfasresponse/Health-Based_Drinking_Water_Value_Recommendations_for_PFAS_in_Michigan_Report_659258_7.pdf.

[60] Agency for Toxic Substances & Disease Registry, U.S. Dep't of Health & Human Servs., *Toxicological Profile for Perfluoroalkyls*, https://www.atsdr.cdc.gov/toxprofiles/tp.asp?id=1117&tid=237 (last updated Sept. 26, 2019).

[61] Mich. Sci. Advisory Workgroup, *supra* note 6, at 26.

[62] Mass. Dep't of Envtl. Prot., *Proposed Amendments and Public Comment, The Massachusetts Drinking Water Regulations, 310 C.M.R. 22.00*, https://www.mass.gov/regulations/310-CMR-22-the-massachusetts-drinking-water-regulations#proposed-amendments-public-comment (last accessed Jun. 2, 2020).

[63] The six PFAS included in the MCL are : PFOS, PFOA, perfluorohexanesulfonic acid (PFHxS), perfluorononanoic acid (PFNA), perfluoroheptanoic acid (PFHpA), and perfluorodecanoic acid (PFDA). *Id.*

In February 2020, the California State Water Resources Control Board's (California Water Board) Division of Drinking Water lowered the response levels for PFOA and PFOS contamination in public drinking water systems to 10 ppt for PFOA and 40 ppt for PFOS.[64] These response levels are based on the estimated lifetime risk of one additional case of cancer in 10,000 people due to exposure to each contaminant through drinking water.[65] Where the concentration of a contaminant in a public water source exceeds the response level, a community water system must take the affected water source out of use, treat the water delivered such that it no longer exceeds the response level, or provide written public notification of the exceedance.[66]

The Wisconsin Department of Health Services (Wisconsin DHS) also developed recommended health-based groundwater standards for PFOA and PFOS in 2019.[67] Wisconsin DHS determined that a groundwater standard of a combined concentration of 20 ppt was necessary to protect the health of sensitive populations and to account for immunotoxicity effects.[68] Wisconsin DHS based this recommendation on modeling and studies published after the 2016 HESDs. In January 2020, Wisconsin's Department of Natural Resources was authorized to

---

[64] Cal. Water Bds., *Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS)*, https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/PFOA_PFOS.html (last updated Feb. 25, 2020).

[65] Cal. Water Bds., *Notification Level Issuance: perfluorooctanoic acid (PFOA)* (Feb. 6, 2020), https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/documents/pfos_and_pfoa/pfoa_nl_issuance_jan2020.pdf; Cal. Water Bds., *Notification Level Issuance: perfluorooctanesulfonic acid (PFOS)* (Feb. 6, 2020), https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/documents/pfos_and_pfoa/pfos_nl_issuance_jan2020.pdf.

[66] Cal. Water Bds., *Notification Level Issuance: perfluorooctanoic acid (PFOA)* (Feb. 6, 2020), https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/documents/pfos_and_pfoa/pfoa_nl_issuance_jan2020.pdf; Cal. Water Bds., *Notification Level Issuance: perfluorooctanesulfonic acid (PFOS)* (Feb. 6, 2020), https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/documents/pfos_and_pfoa/pfos_nl_issuance_jan2020.pdf; Cal. Health & Safety Code § 116378(c)(3).

[67] Wis. Dep't of Health Servs., *Recommended Public Health Groundwater Quality Standards: Scientific Support Documents for Cycle 10 Substances* (June 2019), https://www.dhs.wisconsin.gov/publications/p02434v.pdf. Wisconsin DHS recommends public health groundwater quality standards based on the acceptable daily intake of the substance using a scientific review process that is similar to that used by EPA to set drinking water standards. Wis. Stat. § 160.13(2).

[68] *Id.* at 169–70, 190.

proceed with establishing environmental standards for PFOA and PFOS in groundwater, surface water, and public drinking water.[69]

These states' and organizations' analyses of the concentration of PFOA and PFOS that is safe for human consumption, as well as analyses by several other states, indicate that EPA's Health Advisory Level does not adequately protect public health. The States encourage EPA to set a NPDWR and MCL for a combined concentration of PFOA and PFOS that is much lower than the current federal Health Advisory Level of 70 ppt and is appropriately protective of human health.

C. EPA should set drinking water standards for individual PFAS in addition to PFOA and PFOS and evaluate approaches to regulate PFAS as a class.

PFOA and PFOS share important characteristics with other chemicals in the PFAS class. Indeed, other PFAS have been used as replacement chemicals for PFOA and PFOS because of their shared properties.[70] In her testimony before Congress, Dr. Linda Birnbaum, the Director of the National Institute of Human Health Sciences and the National Toxicology Program of the National Institutes of Health at that time, said that the best way to protect public health was to approach PFAS as a class when assessing exposure and biological impact.[71] As mentioned above, the ATSDR established draft minimum risk levels for several individual PFAS, including PFOA, PFOS, perfluorohexanesulfonic acid (PFHxS), and perfluorononanoic acid (PFNA).[72] In addition, consensus statements signed by scientists around the world with expertise in PFAS show that there are potential harms posed by PFAS as a class, and that the adverse health effects of PFAS in drinking water are not limited to PFOA and PFOS.[73] Given that manufacturers

---

[69] Wis. Dep't of Nat. Res., *Wisconsin Natural Resources Board Approves DNR Effort to Create New PFAS Standards* (Jan. 22, 2020), https://dnr.wi.gov/news/releases/article/?id=5021.

[70] U.S. Envtl. Prot. Agency, *Fact Sheet: Draft Toxicity Assessments for GenX Chemicals and PFBS* (Nov. 2018), https://www.epa.gov/sites/production/files/2018-11/documents/factsheet_pfbs-genx-toxicity_values_11.14.2018.pdf.

[71] *The Federal Role in the Toxic PFAS Chemical Crisis: Hearing Before the Subcomm. on Federal Spending Oversight and Emergency Management of the Senate Comm. on Homeland Security and Governmental Affairs* (Sept. 26, 2018), https://www.hsgac.senate.gov/imo/media/doc/Birnbaum%20Testimony.pdf.

[72] Agency for Toxic Substances & Disease Registry, U.S. Dep't of Health & Human Servs., *Minimum Risk Levels (MRLs) for Hazardous Substances* (Mar. 2020), https://www.atsdr.cdc.gov/mrls/mrllist.asp.

[73] Martin Sheringer et al., *Helsingør Statement on Poly- and Perfluorinated Alkyl Substances (PFASs)*, 114 Chemosphere 337 (2014); Arlene Blum et al., *The Madrid*

may substitute a regulated chemical with a similar, but unregulated one within the PFAS class, it is crucial that EPA expeditiously establish drinking water standards for other PFAS in addition to PFOA and PFOS, as well as evaluate approaches to regulate PFAS as a class, in order to protect public health and ensure safe drinking water.

Several states have proactively sought to protect their waters from a variety of PFAS in addition to PFOA and PFOS. The following are examples of state PFAS standards and additional state standards are provided in Appendix A. In 2018, New Jersey became the first state to promulgate a drinking water standard for any PFAS when it adopted a drinking water standard for PFNA at 13 ppt.[74] In May 2019, Vermont's state legislature called for regulation of five specific chemicals in drinking water: PFOA, PFOS, PFHxS, PFNA, and perfluoroheptanoic acid (PFHpA).[75] This year, Vermont's Agency of Natural Resources adopted an MCL of 20 ppt combined for these five PFAS.[76] In June 2019, Michigan announced it would develop regulatory drinking water standards for seven PFAS chemicals based on current science on PFAS and human health.[77] Specifically, Michigan has identified health-based values to regulate PFOA, PFOS, PFHxS, PFNA, PFHxA, perfluorobutanesulfonic acid (PFBS), and a PFOA replacement chemical known as GenX in drinking water.[78] Further, Michigan's Science Advisory Workgroup also recommended the State aim to reduce contamination of other long-chain PFAS when found at levels above 6 ppt.[79] Similarly, the Governor of Pennsylvania established a PFAS Action Team with the goal of providing every Pennsylvanian safe drinking water.[80] As part of the plan to set a maximum contaminant level for

---

Statement on Poly- and Perfluoroalkyl Substances (PFASs), 123 Envtl. Health Persp. A107 (2015).

[74] N.J. Dep't of Health, *Drinking Water Facts: Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water*, https://www.nj.gov/health/ceohs/documents/pfas_drinking%20water.pdf (last updated Jan. 2020).

[75] Vt. Dep't of Envtl. Conservation, *PFAS (Per- and Polyfluoroalkyl Substances) Information Page*, https://dec.vermont.gov/water/drinking-water/pfas (last visited Apr. 15, 2020).

[76] Vermont Environmental Protection Rules, Chapter 21, Water Supply Rule (Mar. 17, 2020), https://dec.vermont.gov/sites/dec/files/dwgwp/DW/Water-Supply-Rule-March-17-2020.pdf.

[77] Mich. Dep't of Env't, Great Lakes & Energy, *Michigan moves forward on PFAS in drinking water rules* (June 27, 2019), https://www.michigan.gov/egle/0,9429,7-135-3308_3323-500772--,00.html.

[78] *Id.*

[79] *Id.*

[80] Pa. Governor Tom Wolf, *Wolf Administration Continues to Address PFAS Contamination, Announces First Round of Statewide Sampling Results*, (Dec. 5, 2019), https://www.governor.pa.gov/newsroom/wolf-administration-continues-to-address-pfas-contamination-announces-first-round-of-statewide-sampling-results/.

PFAS, in June 2019, Pennsylvania began sampling for at least six PFAS chemicals: PFOA, PFOS, PFNA, PFHxS, PFBS and PFHpA.[81] And in December 2019, Massachusetts published proposed regulatory drinking water standards for six PFAS chemicals: PFOA, PFOS, PFHxS, PFNA, PFHpA, and perfluorodecanoic acid (PFDA).[82]

The California Water Board, which established notification levels[83] and response levels[84] for PFOA and PFOS,[85] is evaluating notification and response levels for other individual PFAS, including PFHxA, PFHxS, PFBS, PFHpA, PFNA, PFDA and 4,8-dioxia-3H-perfluorononanoic acid (ADONA), a replacement for PFOA.[86] Similarly, after recommending groundwater quality standards for PFOA and PFOS, the Wisconsin DHS is evaluating groundwater enforcement standards

---

[81] *Id.*

[82] Mass. Dep't of Envtl. Prot., *Proposed Amendments and Public Comment, The Massachusetts Drinking Water Regulations, 310 C.M.R. 22.00*, https://www.mass.gov/regulations/310-CMR-22-the-massachusetts-drinking-water-regulations#proposed-amendments-public-comment (last accessed Jun. 2, 2020). The need for such expansion of covered PFAS is amply supported by the data. For example, in February 2019 samples taken from public water supply wells in Ayer, Massachusetts, identified as wells Grove Pond 1, Grove Pond 6, Grove Pond 7, Grove Pond 6 and 7, and Grove Pond 8 (closed) tested for five long-chain PFAS at up to 250 ppt. *See* https://www.ayer.ma.us/sites/ayerma/files/uploads/is_ayers_water_safe.pdf (last accessed June 8, 2020).

[83] "A notification level is a nonregulatory, precautionary health-based measure for concentrations of chemicals in drinking water that warrant notification and further monitoring and assessment. Public water systems are encouraged to test their water for contaminants with notification levels. If the systems test, they are required to report exceedances to their governing boards and are urged by the State Water Board to report this information to customers." Cal. Water Bds., *Fact Sheet: Frequently Asked Questions: Drinking Water Guidelines for PFOA and PFOS* (Oct. 14, 2019), https://www.waterboards.ca.gov/publications_forms/publications/factsheets/docs/pfoa_pfos_guidelines_faq_factsheet.pdf.

[84] "A response level is a nonregulatory, precautionary health-based measure that is set higher than a notification level and represents a recommended level that water systems consider taking a water source out of service or provide treatment if that option is available to them. While the State Water Board continues to assess the scope of contamination based on initial data reporting from the statewide assessment, the response levels for PFOA and PFOS remain at 70 parts per trillion for the total combined concentration of both contaminants, consistent with the U.S. Environmental Protection Agency's Health Advisory Level. The response levels will be updated in the fall of 2019." *Id.*

[85] Cal. Water Bds., *Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS)*, https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/PFOA_PFOS.html (last updated Feb. 25, 2020).

[86] *Id.*

for 34 additional PFAS.[87]

Given the scientific evidence demonstrating the adverse health impacts of PFAS, EPA should also regulate other chemicals within the PFAS class, in addition to PFOA and PFOS, to protect human health and ensure safe drinking water. At a minimum, EPA should evaluate whether to regulate other types of PFAS under the SDWA, including individual PFAS for which sufficient toxicity and occurrence data are available or becomes available, and including either on an individual or class basis (for example, based on structural similarity), those monitored under the UCMR 3,[88] those added to the Toxics Release Inventory under the National Defense Authorization Act of 2020,[89] those listed as chemicals subject to significant new use regulations under the Toxic Substances Control Act, and those PFAS that are routinely quantifiable in drinking water using EPA-validated methods.[90]

In addition, the States request that EPA evaluate approaches to regulate PFAS as a class under the SDWA. EPA already takes a class approach to regulating polychlorinated biphenyls (PCBs) and disinfection byproducts.[91] We urge EPA to follow its own lead as reflected in a 2015 proposed rule, in which EPA included all members of a group of chemical substances containing "PFOA and its higher homologues," which is a subclass of PFAS.[92] Regulating PFAS as a class would protect human health more efficiently and effectively than regulating individual PFAS. Because polyfluoroalkyl substances are known, or are theoretically able, to break down to perfluoroalkyl substances, EPA must also regulate these precursors in order to effectively regulate the concentrations of PFOA and PFOS in drinking

---

[87] Wis. Dep't of Natural Res., *Wisconsin Natural Resources Board Approves DNR Effort to Create New PFAS Standards* (Jan. 22, 2020), https://dnr.wi.gov/news/releases/article/?id=5021.

[88] Data collected for PFNA, PFHxS, PFHpA, and PFBS under the UCMR 3 could substantiate preliminary determinations to regulate those chemicals. (*Third Unregulated Contaminant Monitoring Rule*, United States Environmental Protection Agency, https://www.epa.gov/dwucmr/third-unregulated-contaminant-monitoring-rule (last visited Apr. 22, 2020); See Appendix A.)

[89] U.S. Envtl. Prot. Agency, *Chemicals Added to the Toxics Release Inventory Pursuant to Section 7321 of the National Defense Authorization Act*, https://www.epa.gov/sites/production/files/2020-04/documents/tri_non-cbi_pfas_list_2_19_2020_final_clean.pdf.

[90] 40 CFR Part 721 and Subpart E and 85 Fed. Reg. 12479 (March 3, 2020) (proposed rule).

[91] U.S. Envtl. Prot. Agency, *National Primary Drinking Water Regulations,* https://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations (last updated Feb. 14, 2020).

[92] U.S. Envtl. Prot. Agency, *Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule*, https://www.federalregister.gov/documents/2015/01/21/2015-00636/long-chain-perfluoroalkyl-carboxylate-and-perfluoroalkyl-sulfonate-chemical-substances-significant.

water. A class-based approach would also be more effective than regulating PFAS chemicals individually because it would prevent manufacturers from simply replacing each regulated PFAS chemical with one of the thousands of unregulated PFAS chemicals that have similar harmful qualities or may transform into regulated PFAS chemicals.[93]

D. Expeditious promulgation of final drinking water standards for PFAS is necessary to protect public health.

The States strongly urge EPA to exercise its authority under the SDWA to publish proposed maximum contaminant level goals and proposed national primary drinking water regulations for PFOA and PFOS concurrently with its final determination to regulate the contaminants. Expediting the development of final drinking water standards for PFOA and PFOS is necessary to protect public health, due to the bio-accumulative and persistent nature of the contaminants and their widespread presence in public drinking water systems. Furthermore, EPA has already gathered and analyzed sufficient data regarding the characteristics of the contaminants, the risks that they pose to human health, and the extent of their occurrence in public drinking water systems to support the expedited promulgation of national primary drinking water regulations for PFOA and PFOS.

The SDWA sets time limits for promulgating these standards. Pursuant to the SDWA, within 24 months of publishing a final determination to regulate PFOA and PFOS, EPA must issue proposed rules establishing maximum contaminant level goals and national primary drinking water standards for the contaminants.[94] After EPA makes these proposals, it has an additional 18 months to publish a final maximum contaminant level goal and a national primary drinking water regulation.[95] In addition, as repeatedly noted in the Preliminary Regulatory Determination, EPA may further extend this deadline by up to nine months.[96] As a result, once EPA makes a final determination to regulate PFOA and PFOS, EPA could take an additional 4.25 years to promulgate legally enforceable drinking water standards designed to limit PFOA and PFOS contamination in public water systems.[97] However, under the SDWA, EPA is authorized to publish a proposed

---

[93] Several thousands of PFAS are known to exist. *See* Concawe, *supra* at 10. Given the sheer quantity of PFAS chemicals, it would be impracticable to regulate each individually.
[94] SDWA § 1412(b)(1)(E); 42 U.S.C. § 300g-1(b)(1)(E).
[95] SDWA § 1412(b)(1)(E); 42 U.S.C. § 300g-1(b)(1)(E).
[96] SDWA § 1412(b)(1)(E); 42 U.S.C. § 300g-1(b)(1)(E); *see also* Preliminary Determination, 85 Fed. Reg. at 14,100 n.3, 14,107 n.18, 14,135.
[97] Preliminary Determination, 85 Fed. Reg. at 14,135 (according to the Preliminary Determination, if EPA makes a final determination to regulate PFOS or PFOA, it "intends

maximum contaminant level goal and a proposed national primary drinking water regulation concurrently with its final determination to regulate.[98] We therefore urge EPA to act expeditiously in finalizing these standards.

The SDWA's requirement limiting the time period between a final determination to regulate and the promulgation of a national primary drinking water standard is intended to expedite the regulatory process to the extent practicable, while allowing EPA to collect necessary data and conduct analysis regarding the adverse effects of the contaminant on human health, the frequency of the contaminant's occurrence in public water systems at levels of public health concern, and whether regulation of the contaminant presents a meaningful opportunity for health risk reduction.[99] As the Preliminary Determination acknowledges, PFOA and PFOS have been widely studied and the scientific research on PFOA and PFOS is already well-developed.[100]

The urgency of promulgating standards is amply supported by existing data that show extensive PFOA and PFOS contamination in public drinking water systems across the country.[101] This contamination is especially concerning because "PFOS and PFOA are resistant to environmental degradation processes such as hydrolysis, photolysis, and biodegradation and are thus highly persistent in the environment."[102] As a result, without treatment, PFOA and PFOS contamination will continue to worsen and will persist in drinking water sources indefinitely. Due to the harmful effects of PFOA and PFOS in drinking water, swift promulgation of stringent final drinking water standards is crucial to enable EPA to take effective regulatory enforcement actions to address PFAS contamination.

As discussed above, the deadlines set forth in the SDWA allow for an additional 4.25-year delay in the promulgation of national primary drinking water regulations for PFOA and PFOS. Such delay is unnecessary, would needlessly increase the public health risk that these contaminants pose, and would ultimately require more costly and extensive treatment. Accordingly, the States urge EPA to

---

to propose an NPDWR within 24 months and promulgate a final NPDWR within 18 months following the proposal," with the possibility of an additional nine-month extension).

[98] SDWA § 1412(b)(1)(E); 42 U.S.C. § 300g-1(b)(1)(E).

[99] The SDWA was amended to include these deadlines in 1986 in order to expedite the standard-setting process). 132 Cong. Rec. S6284-02, 1986 WL 793998 (May 21, 1986) (statement of Rep. Durenberger). "The development of the CCL, regulatory determinations, and any subsequent rulemaking should be viewed as a progression where each process builds upon the previous process, including the collection of data and analyses conducted." Preliminary Determination, 85 Fed. Reg. at 14,100.

[100] *Id.* at 14,115.

[101] *See, e.g., id.* at 14,118.

[102] *Id.* at 14,119.

publish proposed maximum contaminant level goals and national primary drinking water standards for PFOA and PFOS concurrently with its final determination to regulate, and to issue final drinking water standards for the contaminants as expeditiously as practicable, but no later than 18 months from the time the final determination to regulate is made.

In addition, the States request that EPA include chemicals in the PFAS class, other than PFOA and PFOS, on the Contaminant Candidate List 5 ("CCL 5") and the Contaminant Candidate List 6 ("CCL 6"). For example and as discussed above, several states, ATSDR, and EFSA have concluded that other long-chain PFAS including PFNA and PFHxS pose similar risks to human health as PFOA and PFOS when present at equal concentrations. Additionally, because chemicals in the PFAS class share similar characteristics, manufacturers may easily substitute PFOA and PFOS with other chemicals in the PFAS class. However, these replacement chemicals, and many other PFAS, have been shown to pose similar risks to human health as PFOA and PFOS and some are known to break down or transform into PFOA and PFOS.[103] As a result, it is crucial that EPA expeditiously promulgate drinking water standards for other chemicals in the PFAS class in addition to PFOA and PFOS in order to protect public health. Including these chemicals on the CCL 5 and CCL 6 is the first step in this process.[104]

E. Conclusion

The States appreciate the opportunity to comment on EPA's Preliminary Determination to regulate PFOA and PFOS under the SDWA. We agree with EPA's Preliminary Determination to regulate PFOA and PFOS. We respectfully request that EPA promulgate a drinking water standard for PFOA and PFOS that

---

[103] Martin Sheringer et al., *Helsingør Statement on Poly- and Perfluorinated Alkyl Substances (PFASs)*, 114 CHEMOSPHERE 337 (2014); Arlene Blum et al., *The Madrid Statement on Poly- and Perfluoroalkyl Substances (PFASs)*, 123 ENVTL. HEALTH PERSP. A107 (2015); Buck et al., *Perfluoroalkyl and polyfluoroalkyl substances in the environment: terminology, classification, and origins*, INTEGRATED ENVTL. ASSESSMENT AND MGMT. 7 (4), 513–541 (2011), https://www.ncbi.nlm.nih.gov/pubmed/21793199; Concawe, *Environmental Fate and Effects of Poly- and Perfluoroalkyl Substances (PFAS)*, Report No. 8/16 - Environmental Science for the European Refining Industry (2016), https://www.concawe.eu/wp-content/uploads/2016/06/Rpt_16-8.pdf.

[104] Although EPA has not yet announced the Final CCL 5, the deadline for nominations, December 4, 2018, has passed. (*Contaminant Candidate List 5 (CCL 5)*, United States Environmental Protection Agency, https://www.epa.gov/ccl/contaminant-candidate-list-5-ccl-5 (last visited Apr. 22, 2020).) The States therefore encourage EPA to include on the CCL 5 all chemicals in the PFAS class that were nominated for consideration. The States further encourage EPA to consider the inclusion of additional chemicals in the PFAS class on the CCL 6.

sufficiently protects public health, consider regulation of PFAS as a class and other individual PFAS under the SDWA, and expedite issuance of final drinking water standards.

Sincerely,

FOR THE STATE OF WISCONSIN

JOSHUA L. KAUL
Attorney General of Wisconsin

By: */s/ Sarah C. Geers*
SARAH C. GEERS
BRADLEY J. MOTL
Assistant Attorneys General
Wisconsin Department of Justice
Post Office Box 7857
Madison, Wisconsin 53707-7857
Phone: (608) 266-3067
Email: geerssc@doj.state.wi.us

FOR THE STATE OF CALIFORNIA

XAVIER BECERRA
Attorney General

By: /s/ *Sarah E. Morrison*
SARAH E. MORRISON
Supervising Deputy Attorney General
LANI M. MAHER
ROXANNE J. CARTER
Deputy Attorneys General
California Department of Justice
300 South Spring Street, Suite 1702
Los Angeles, CA 90013
Phone: (213) 269-6328
Email: Sarah.Morrison@doj.ca.gov

FOR THE COMMONWEALTH OF PENNSYLVANIA

JOSH SHAPIRO
Attorney General of Pennsylvania

By: /s/ *Ann Johnston*
ANN JOHNSTON
Senior Deputy Attorney General
Office of Attorney General
Strawberry Square 14th Floor
Harrisburg, PA 17120
Phone: (717)705-6938
Email: ajohnston@attorneygeneral.gov

FOR THE STATE OF COLORADO

PHIL WEISER
Attorney General of Colorado

By: /s/ *Amy Beatie*
AMY BEATIE
Deputy Attorney General
Colorado Department of Law
Natural Resources and Environment Section
Ralph L. Carr Colorado Judicial Center
1300 Broadway, 10th Floor
Denver, Colorado 80203
Phone: (720) 508-6295
Email: amy.beatie@coag.gov

FOR THE STATE OF CONNECTICUT

WILLIAM TONG
Attorney General of Connecticut

By: /s/ *Jill Lacedonia*
JILL LACEDONIA
Assistant Attorney General
Connecticut
Office of the Attorney General
165 Capitol Avenue
Hartford, CT 06106
Phone: (860) 808-5250
Email: Jill.Lacedonia@ct.gov

FOR THE STATE OF DELAWARE

KATHLEEN JENNINGS
Attorney General of Delaware

By: /s/ *Christian Douglas Wright*
CHRISTIAN DOUGLAS WRIGHT
Director of Impact Litigation
Delaware Department of Justice
820 N. French Street, 5th Floor
Wilmington, DE 19801
Phone: (302) 577-8600
Email: christian.wright@delaware.gov

FOR THIS DISTRICT OF COLOMBIA

KARL A. RACINE
Attorney General of the District of Colombia

By: /s/ *Kathleen Konopka*
Kathleen Konopka
Deputy Attorney General
Office of the Attorney General
for the District of Columbia
441 Fourth Street N.W.
Suite 650 North
Washington, D.C. 20001
Email: Kathleen.Konopka@dc.gov

FOR THE STATE OF ILLINOIS

KWAME RAOUL
Attorney General of Illinois

By: /s/ *Jason E. James*
JASON E. JAMES
Assistant Attorney General
MATTHEW DUNN
Chief, Environmental Enforcement/
Asbestos Litigation Division
69 W. Washington St., 18th Floor
Chicago, IL 60602
Phone: (312) 814-0660
Email: jjames@atg.state.il.us

FOR THE STATE OF IOWA

TOM MILLER
Attorney General of Iowa

By: /s/ *David S. Steward*
DAVID S. STEWARD
Assistant Attorney General
Iowa Attorney General's Office
1305 E. Walnut St., Second Fl.
Des Moines, IA 50319
Phone: (515) 281-7242
Email: david.steward@ag.iowa.gov

FOR THE STATE OF MAINE

AARON M. FREY
Attorney General of Maine

By: /s/ *Katherine Tierney*
KATHERINE TIERNEY
Assistant Attorney General
Office of the Attorney General
6 State House Station
Augusta, Maine 04333
Phone: (207) 626-8897
Email: katherine.tierney@maine.gov

FOR THE STATE OF MARYLAND

BRIAN E. FROSH
Attorney General of Maryland

By: /s/ *Steven J. Goldstein*
Steven J. Goldstein
Special Assistant Attorney General
Office of the Attorney General
200 Saint Paul Place, 20th Floor
Baltimore, Maryland 21202
Phone: (410) 576-6414
Email: sgoldstein@oag.state.md.us

FOR THE COMMONWEALTH OF MASSACHUSETTS

MAURA HEALEY
Attorney General of Massachusetts

By: /s/ *I. Andrew Goldberg*
I. ANDREW GOLDBERG
Assistant Attorney General
Environmental Protection Division
Massachusetts Attorney General's Office
One Ashburton Place, 18th Flr.
Boston, MA 02108
Phone: (617) 963-2429
Email: andy.goldberg@mass.gov

FOR THE STATE OF MINNESOTA

KEITH M. ELLIISON
Attorney General of Minnesota

By: /s/ *Peter N. Surdo*
PETER N. SURDO
Special Assistant Attorney General
Office of the Minnesota Attorney General
445 Minnesota Street, Suite 1400
Saint Paul, Minnesota 55101
Phone: (651) 757-1061
Email: peter.surdo@ag.state.mn.us

FOR THE STATE OF NEVADA

AARON D. FORD
Attorney General of Nevada

By: /s/ Heidi Parry Stern
Heidi Parry Stern
Solicitor General
Office of the Nevada Attorney

General
555 E. Washington Ave., Ste. 3900
Las Vegas, NV 89101
Email: HStern@ag.nv.gov

FOR THE STATE OF NEW JERSEY

GURBIR S. GREWAL
Attorney General of New Jersey

By: /s/ *Gwen Farley*
GWEN FARLEY
Deputy Attorney General
Department of Law and Public Safety
Division of Law
R.J. Hughes Justice Complex
25 Market Street, 7th floor
Trenton, New Jersey 08625-0093
Phone: (609) 376-2740
Email: gwen.farley@law.njoag.gov

FOR THE STATE OF NEW MEXICO

HECTOR BALDERAS
Attorney General of New Mexico

By: */s/ William Grantham*
WILLIAM GRANTHAM
Assistant Attorney General
Consumer & Environmental
Protection Division
201 Third Street NW, Suite 300
Albuquerque, New Mexico 87102
Phone: (505) 717-3520
Email: wgrantham@nmag.gov

FOR THE STATE OF NEW YORK

LETITIA JAMES
Attorney General of New York

By: /s/ *Mihir A. Desai*
MIHIR A. DESAI
Assistant Attorney General
PHILIP BEIN
Senior Counsel
New York State Office
of the Attorney General
28 Liberty Street, 19th Floor
New York, NY 10005
Phone: (212) 416-8446
Email: mihir.desai@ag.ny.gov
Email: philip.bein@ag.ny.gov

FOR THE STATE OF
NORTH CAROLINA

JOSHUA H. STEIN
Attorney General of North Carolina

By: /s/ *Marc Bernstein*
MARC BERNSTEIN
Special Deputy Attorney General
North Carolina Department of Justice
Post Office Box 629
Raleigh, North Carolina 27602-0629
Phone: (919) 716-6956
Email: mbernstein@ncdoj.gov

FOR THE STATE OF OREGON

ELLEN F. ROSENBLUM
Attorney General of Oregon

By: /s/ *Paul Garrahan*
PAUL GARRAHAN
Attorney-in-Charge,
Natural Resources Section
Oregon Department of Justice
1162 Court Street, N.E.
Salem, OR 97301-4096
Telephone: (503) 947-4593

Fax: (503) 378-3784
Email: Paul.Garrahan@doj.state.or.us

FOR THE STATE OF
RHODE ISLAND

PETER F. NERONHA
Attorney General of Rhode Island

By: /s/ *Alison B. Hoffman*
ALISON B. HOFFMAN
Special Assistant Attorney General
Rhode Island Office of the Attorney General
150 South Main Street
Providence, RI 02903
Phone: (401) 274-4400 ext 2116
Email: ahoffman@riag.ri.gov

FOR THE COMMONWEALTH OF
VIRGINIA

MARK R. HERRING
Attorney General of Virginia

By: /s/ *Christopher E. Bergin*
Christopher E. Bergin
Assistant Attorney General
Environmental Section
202 N. 9th Street
Richmond, Virginia 23219
Phone: (804) 786-8480
Email: cbergin@oag.state.va.us

FOR THE STATE OF WASHINGTON

BOB FERGUSON
Attorney General of Washington

By: /s/ *Ivy Anderson*
IVY ANDERSON
Assistant Attorney General
Ecology Division
2425 Bristol Court SW
Olympia Washington 98504-0117
Phone: (360) 586-4619
Email: ivy.anderson@atg.wa.gov

EXHIBIT

C-138

Congressional Research Service
Informing the legislative debate since 1914

PFAS and Drinking Water: Selected EPA and Congressional Actions

Elena H. Humphreys
Analyst in Environmental Policy

Mary Tiemann
Specialist in Environmental Policy

July 2, 2019

Congressional Research Service
7-....
www.crs.gov
R45793

CRS REPORT
Prepared for Members and
Committees of Congress

Congressional Research Service
Informing the legislative debate since 1914

SUMMARY

PFAS and Drinking Water: Selected EPA and Congressional Actions

R45793

July 2, 2019

Elena H. Humphreys
Analyst in Environmental Policy
-re-acte--@crs.loc.gov

Mary Tiemann
Specialist in Environmental Policy
-re-acte--@crs.loc.gov

Per- and polyfluoroalkyl substances (PFAS) are fluorinated chemicals that have been used in an array of commercial, industrial, and U.S. military applications for decades. Some of the more common applications include nonstick coatings, food wrappers, waterproof materials, and fire suppressants. Detections of some PFAS in drinking water supplies and uncertainty about potential health effects associated with exposure to particular PFAS above certain concentrations have increased calls for the U.S. Environmental Protection Agency (EPA) to address these substances in public water supplies. For those few PFAS for which scientific information is available, animal studies suggest that exposure to particular substances above certain levels may be linked to various health effects, including developmental effects; changes in liver, immune, and thyroid function; and increased risk of some cancers. In 2009, EPA listed certain PFAS for formal evaluation under the Safe Drinking Water Act (SDWA) to determine whether regulations may be warranted. EPA has not issued drinking water regulations for any PFAS but has taken various actions to address PFAS contamination.

In the 116th Congress, Members have introduced more than 35 bills to address PFAS through various means. Multiple bills would direct EPA to take regulatory and other actions to address these emerging contaminants under several environmental statutes, including SDWA. Several SDWA-related bills would direct EPA to establish a drinking water standard for one or more PFAS, require monitoring for PFAS in public water supplies, and authorize grants to communities to treat PFAS in drinking water.

In February 2019, EPA released its PFAS Action Plan, which discusses the agency's current and proposed actions to address these substances under its various statutory authorities. Regarding SDWA, the plan notes that EPA is following the statutory process for evaluating PFAS—particularly perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS)—to determine whether national primary drinking water regulations are warranted. EPA is scheduled to propose preliminary regulatory determinations for PFOA and PFOS by the end of 2019 and to make final determinations by the end of 2020. The plan also reviews other SDWA authorities that the agency is using to address PFAS in drinking water.

The absence of a national health-based drinking water standard for any PFAS has increased interest in the SDWA process for regulating contaminants. The statute prescribes a risk- and science-based process for evaluating and regulating contaminants in drinking water. The evaluation process includes identifying contaminants of potential concern, assessing health risks, collecting occurrence data (and developing reliable analytical methods necessary to do so), and making determinations as to whether a national drinking water regulation is warranted for a contaminant.

PFAS includes thousands of diverse chemicals, and setting scientifically sound drinking water standards for one or multiple PFAS raises technical and scientific challenges. For example, SDWA requires EPA to make determinations and set standards using the best available peer-reviewed science and occurrence data. However, data on the potential health effects and occurrence are available for very few of these substances. Further, EPA may face challenges in developing test methods needed to evaluate PFAS occurrence and technologies to treat PFAS in drinking water. Contamination of drinking water by PFAS can pose challenges for states and communities, and some have called for EPA to establish a health-based standard. State drinking water regulators have noted that many states may face significant obstacles in setting their own standards.

For emerging contaminants not regulated under SDWA, EPA is authorized to issue health advisories, which provide information on health effects, testing methods, and treatment techniques for contaminants of concern. In 2016, EPA established health advisory levels for PFOA and PFOS in drinking water at 70 parts per trillion (separately or combined).

SDWA also authorizes EPA to take actions it deems necessary to abate an imminent and substantial endangerment to public health from a contaminant present in or likely to enter a public water system or an underground source of drinking water. Actions may include issuing orders requiring persons who caused or contributed to the endangerment to provide alternative water supplies or to treat contamination. Since 2002, EPA has used this authority to require responses to PFOA and/or PFOS contamination of water supplies associated with four sites, including three Department of Defense sites.

Contents

Tables

Appendixes

Contacts

Introduction

Detections of per- and polyfluoroalkyl substances (PFAS) in drinking water supplies and concerns about potential health effects associated with exposure to PFAS have increased congressional attention to the U.S. Environmental Protection Agency's (EPA) efforts to address the presence of these substances in public water supplies. Over the past decade, EPA has been evaluating several PFAS under the Safe Drinking Water Act (SDWA) to determine whether national drinking water regulations may be warranted. EPA has not issued SDWA regulations for any PFAS but has taken various actions to address PFAS contamination. Using SDWA authorities, in 2016, EPA issued non-enforceable health advisories for two PFAS—perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS)—in drinking water.[1]

In the 116th Congress, Members have introduced more than 35 bills that would address PFAS exposure through various authorities and agencies. A number of bills would direct EPA to take regulatory and other actions under several environmental statutes, including SDWA. Of the SDWA bills, some would require EPA to establish drinking water standards for PFAS, require monitoring for more of these substances, or authorize grants to assist communities in treating PFAS in drinking water.

PFAS are a large, diverse group of fluorinated compounds, some of which have been used for decades in a wide array of commercial, industrial, and U.S. military applications.[2] Since the 1940s, more than 1,200 PFAS compounds have been used in commerce, and about 600 are still in use today.[3] The chemical characteristics of PFAS have led to the widespread use of these substances for beneficial purposes (such as firefighting) and in the processing and manufacture of many commercial products, such as nonstick cookware, food wrapper coatings, stain-resistant carpets, waterproof clothing, and food containers.

The detection of certain PFAS in surface water, groundwater, and public water supplies in various locations has generated public concern and drawn attention to the use and federal regulation of these chemicals in commerce and in the environment. The two PFAS most frequently detected in water supplies are PFOA and PFOS. Since 2002, U.S. manufacturers have phased out the production and most uses of PFOS.[4] In coordination with EPA, manufacturers completed the phase-out of PFOA production by 2015.[5] EPA reports that food and consumer products represent

[1] In May 2016, EPA established Lifetime Health Advisory levels for PFOA and PFOS at 70 parts per trillion, separately or combined. These non-enforceable levels are expected to protect the most sensitive subpopulations (e.g., nursing infants), with a margin of protection, over a lifetime of exposure. Health advisories are non-regulatory and are intended to help states, water suppliers, and others address contaminants for which federal (or state) drinking water standards have not been established.

[2] These chemical compounds consist of a chain of carbon atoms generally attached to varying numbers of fluorine atoms. Fully fluorinated chemicals are referred to as perfluoroalkyl substances, while partially fluorinated chemicals are referred to as polyfluoroalkyl substances. Among potentially thousands of PFAS, differences in the length of the carbon chain, number of fluorine atoms, and other structural parts of the PFAS suggest that there may also be differences in terms of their properties, uses, interactions with other chemicals in the environment, and health effects in humans. More information regarding the chemical and physical properties of certain PFAS are available in Chapter 4 of Agency of Toxic Substances and Disease Registry, *Toxicological Profile for Perfluoroalkyls, Draft for Public Comment*, June 2018, https://www.atsdr.cdc.gov/toxprofiles/tp.asp?id=1117&tid=237.

[3] EPA, *EPA's Per- and Polyfluoroalkyl Substances (PFAS) Action Plan*, February 2019, p. 12, https://www.epa.gov/pfas/epas-pfas-action-plan.

[4] EPA, "Perfluoroalkyl Sulfonates; Significant New Use Rule," 67 *Federal Register* 11007, March 11, 2002.

[5] EPA initiated the 2010/2015 PFOA stewardship program in January 2006 (EPA-HQ-OPPT-2006-0621). EPA invited the eight companies manufacturing PFOA and associated chemicals to reduce their PFOA product content and

a large portion of exposure to PFOA and PFOS, while drinking water can be an additional source in the small percentage of communities with contaminated water supplies.[6]

Among the thousands of different PFAS, few have sufficient health effects studies for determining a threshold at which adverse effects are not expected to occur. Most studies of potential health effects of PFAS have focused on PFOA and PFOS because of their predominant historical use. For those PFAS for which scientific information is available, animal studies suggest that exposure to particular substances above certain levels may be linked to various health effects, including developmental effects; changes in liver, immune, and thyroid function; and increased risk of some cancers.[7] A discussion of these studies and their results is beyond the scope of this report.

In 2016, EPA reported that public water systems in 29 states had detected at least one PFAS in their water supplies.[8] In total, 63 public water systems serving approximately 5.5 million people reported detections of PFOA and PFOS (separately or combined) above EPA's health advisory level of 70 parts per trillion (ppt).[9] EPA has reported that PFAS contamination of drinking water "is typically localized and associated with a specific facility."[10] According to the Agency of Toxic Substances and Disease Registry, PFAS may have been released to surface or ground water from manufacturing sites, industrial use, use and disposal of PFAS-containing consumer products (e.g., unlined landfills), fire/crash training areas, wastewater treatment facilities, and the spreading of contaminated biosolids.[11] A discussion of PFAS use, including at U.S. military installations, and PFAS disposal is not included in this report.

Uncertainty about potential health effects that may be associated with exposure to specific PFAS above particular concentrations—combined with the absence of a federal health-based drinking water standard—has posed challenges and created uncertainty for states, water suppliers and their customers, homeowners using private wells, and others regarding treatment or other responses.[12] State drinking water regulators and others have called for greater federal leadership to address these substances through several federal laws and, specifically, have urged EPA to set federal

---

emission by 95% by 2010 and eliminate their PFOA emissions and product content by 2015. EPA reported that all companies met the stewardship program's goals.

[6] EPA, *Health Effects Support Document for Perfluorooctane Sulfonate (PFOS)*, May 2016; EPA, *Health Effects Support Document for Perfluorooctanoic Acid (PFOA)*, May 2016; and EPA, *PFOA & PFOS Drinking Water Health Advisories, Fact Sheet*, November 2016, p. 1. EPA required roughly 5,000 water systems (that serve approximately 82% of U.S. population) to monitor for six PFAS—including PFOA and PFOS—between January 2013 and December 2015. According to EPA, 63 water systems (1.3%) serving an estimated 5.5 million individuals detected PFOA and/or PFOS at levels above EPA's health advisory level of 70 ppt (separately or combined). Monitoring results for individual water systems are available at https://www.epa.gov/dwucmr/third-unregulated-contaminant-monitoring-rule.

[7] EPA, Health Effects Support Document for Perfluorooctane Sulfonate (PFOS), May 2016; EPA, Health Effects Support Document for Perfluorooctanoic Acid (PFOA), May 2016.

[8] Monitoring results for individual water systems are available at https://www.epa.gov/dwucmr/third-unregulated-contaminant-monitoring-rule.

[9] Email communication with EPA, May 30, 2019. This health advisory level is expected to be protective of sensitive subpopulations, with a margin of protection, assuming daily ingestion at this concentration over a lifetime (70 years).

[10] EPA, *PFOA & PFOS Drinking Water Health Advisories, Fact Sheet*, November 2016, p. 1.

[11] Agency for Toxic Substances and Disease Registry, *Toxicological Profile for Perfluoroalkyls, Draft for Public Comment*, June 2018, ch. 5, https://www.atsdr.cdc.gov/toxprofiles/tp.asp?id=1117&tid=237.

[12] See for example, testimony of Tracy Mehan for the American Water Works Association before the Senate Committee on Environmental and Public Works, hearing on Examining Legislation to Address the Risks Associated with Per- and Polyfluoroalkyl Substances (PFAS), May 22, 2019, https://www.epw.senate.gov/public/index.cfm/2019/5/examining-legislation-to-address-the-risks-associated-with-per-and-polyfluoroalkyl-substances-pfas.

drinking water standards for one or more PFAS under SDWA.[13] Representatives of public water systems have supported EPA's commitment to follow the statutory process for regulating contaminants in drinking water, which prioritizes regulating those that occur at levels and frequency of public health concern.[14]

SDWA provides EPA with several authorities to address emerging contaminants in public water supplies and drinking water sources. These include the authority to (1) issue health advisories, (2) regulate contaminants in water provided by public water systems, and (3) issue enforcement orders in certain circumstances.[15] For more than a decade, EPA has been using SDWA authorities to evaluate several PFAS—particularly PFOA and PFOS—to determine whether national drinking water regulations may be warranted.[16] To date, EPA has not promulgated drinking water regulations for any PFAS but has taken a number of related actions.

In February 2019, EPA issued a PFAS Action Plan, which identifies and discusses the agency's current and proposed efforts to address PFAS through several statutory authorities, including SDWA.[17] These actions range from potential regulatory actions to public outreach on PFAS. Many of these actions support EPA's evaluation of PFAS for potential regulation under SDWA. These include research and development of analytical methods needed to accurately measure substances in drinking water, development of additional toxicity information to increase understanding of potential health risks associated with exposures to different PFAS, and research on drinking water treatment effectiveness and costs for various PFAS. EPA also plans to generate occurrence data for more PFAS to determine their frequencies and concentrations in public water supplies. Further, EPA is working with federal, state, and tribal partners to develop risk communication materials on PFAS and plans to develop an interactive map on potential PFAS sources and occurrence. **Table A-1** includes EPA's selected actions and associated timelines relevant to addressing PFAS in drinking water.

The challenges of regulating individual substances or categories of PFAS in drinking water are multifaceted and may raise several policy and scientific questions. Technical issues involve availability of data, detection methods, and treatment techniques for related but diverse contaminants. Scientific questions exist about health effects attributed to many individual PFAS and whether health effects can be generalized from one or a category of PFAS to others. Policy and regulatory considerations may involve setting priorities among numerous unregulated contaminants, the value of establishing uniform national drinking water standards, and the ability

---

[13] See for example, testimony of Lisa Daniels for the Association of State Drinking Water Administrators before the Senate Committee on Environmental and Public Works, hearing on Examining Legislation to Address the Risks Associated with Per- and Polyfluoroalkyl Substances (PFAS), May 22, 2019, https://www.epw.senate.gov/public/index.cfm/2019/5/examining-legislation-to-address-the-risks-associated-with-per-and-polyfluoroalkyl-substances-pfas.

[14] See for example, testimony of Mehan.

[15] SDWA Section 1412(b)(1)(F)—Title 42, Section 300g-1(b)(1)(F) of the *United States Code*—authorizes EPA to establish health advisories for emerging drinking water contaminants. SDWA Section 1412 (42 U.S.C. §300g-1) authorizes EPA to regulate contaminants in drinking water. SDWA Section 1431 (42 U.S.C. §300i) authorizes EPA to issue emergency orders to address drinking water contamination, under certain circumstances. SDWA provides additional tools to address emerging contaminants, such as source water assessment and protection programs.

[16] Using Toxic Substance Control Act (TSCA) authorities, EPA has issued several significant new use rules that require manufacturers (including importers) and processors of certain PFAS to notify EPA at least 90 days prior to resuming use of these substances. EPA then would review the potential health and environmental effects of the activity and make a determination whether to authorize the new use.

[17] EPA, *EPA's Per- and Polyfluoroalkyl Substances (PFAS) Action Plan*, February 2019, https://www.epa.gov/pfas/epas-pfas-action-plan. The plan also notes the agency's actions under the authority of other environmental statutes, including the Clean Air Act; the Clean Water Act; the Comprehensive Environmental Response, Compensation, and Liability Act; the Resource Conservation and Recovery Act; and TSCA.

to demonstrate the relative risk-reduction benefits compared to compliance costs to communities associated with regulating individual or multiple PFAS.[18] The absence of a federal health-based standard can pose challenges for states and communities with PFAS contamination. State drinking water regulators have noted that many states may face significant obstacles in setting their own standards.

This report provides an overview of EPA's ongoing and proposed actions to address PFAS under SDWA authorities, with particular focus on the statutory process for evaluating PFAS—particularly PFOA and PFOS—for potential regulation. It also reviews PFAS-related legislation introduced in the 116th Congress. This report does not address the status of scientific research on health effects that may be associated with exposure to one or more PFAS, nor does it discuss federal actions regarding other environmental statutes, such as the Toxic Substances Control Act (TSCA) and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA).[19]

Addressing PFAS Using SDWA Authorities

SDWA provides EPA with several authorities to address emerging contaminants in drinking water supplies and sources. The act authorizes EPA to promulgate regulations that include enforceable standards and monitoring requirements for contaminants in water provided by public water systems.[20] For contaminants that are not regulated under the act, SDWA authorizes EPA to issue contaminant-specific health advisories that include technical guidance and identify concentrations that are expected to be protective of sensitive populations.[21] In addition, if the appropriate state and local authorities have not acted to protect public health, SDWA authorizes EPA to take actions to abate an imminent and substantial endangerment to public health from "a contaminant that is present in or is likely to enter a public water system or an underground source of drinking water."[22]

Evaluating Emerging Contaminants for Regulation

SDWA specifies a multistep process for evaluating contaminants to determine whether a national primary drinking water regulation is warranted.[23] The evaluation process includes identifying contaminants of potential concern, assessing health risks, collecting occurrence data (and developing reliable analytical methods necessary to do so), and making determinations as to whether or not regulatory action is needed for a contaminant.

---

[18] When developing regulations, SDWA requires EPA to (1) use the best available peer-reviewed science and supporting studies and data and (2) make publicly available a risk assessment document that discusses estimated risks, uncertainties, and studies used in the assessment. When proposing drinking water regulations, EPA must publish a "health risk reduction and cost analysis." For each drinking water standard and each alternative standard being considered for a contaminant, EPA must publish and take comment on quantifiable and nonquantifiable health risk reduction benefits and costs and also conduct other specified analyses (SDWA §1412(b); 42 U.S.C. §300g-1(b).

[19] For more information on the regulation of chemicals in commerce under TSCA, see CRS Report RL31905, *The Toxic Substances Control Act (TSCA): A Summary of the Act and Its Major Requirements*, by Jerry H. Yen.

[20] SDWA §1412; 42 U.S.C. §300g-1. SDWA does not cover residential wells.

[21] SDWA §1412(b)(1)(F); 42 U.S.C. §300g-1(b)(1)(F).

[22] SDWA §1431; 42 U.S.C. §300i.

[23] SDWA §1412; 42 U.S.C. §300g-1.

To make a positive determination that a national drinking water regulation is warranted for a contaminant, EPA must find that

- a contaminant may have an adverse health effect;
- it is known to occur or there is a substantial likelihood that it will occur in public water systems with a frequency and at levels of public health concern; and
- in the sole judgment of the EPA Administrator, regulation of the contaminant presents a meaningful opportunity for health risk reduction for persons served by water systems.[24]

Identifying Contaminants That May Warrant Regulation

SDWA Section 1412(b) requires EPA to publish, every five years, a list of contaminants that are known or anticipated to occur in public water systems and may require regulation under the act.[25] Before publishing a final contaminant candidate list (CCL), EPA is required to provide an opportunity for public comment and consult with the scientific community, including the Science Advisory Board.[26]

In 2009, EPA placed PFOA and PFOS on the third such list (CCL 3) for evaluation.[27] In preparing the CCL 3, EPA considered over 7,500 chemical and microbial contaminants and screened these contaminants based on their potential to occur in public water systems and potential health effects. EPA selected 116 of the contaminants on the proposed CCL based on more detailed evaluation of occurrence, health effects, expert judgement, and public input.[28]

In 2016, EPA published the fourth list, CCL 4, which carried over many CCL 3 contaminants, including PFOA and PFOS. EPA carried forward these contaminants to continue evaluating health effects, gathering national occurrence data, and developing analytical methods.[29]

Monitoring for Emerging Contaminants in Public Water Systems

To generate data on the nationwide occurrence of emerging contaminants in public water supplies, EPA is required to administer a monitoring program for unregulated contaminants. SDWA directs EPA to promulgate, every five years, an unregulated contaminant monitoring rule (UCMR) that requires public water systems to test for no more than 30 contaminants.[30] Only a representative sample of systems serving 10,000 or fewer people is required to conduct

---

[24] SDWA §1412(b)(1)(A); 42 U.S.C. §300g-1(b)(1)(A). The Administrator's determination whether or not to regulate a contaminant is not subject to judicial review (SDWA §1412(b)(1)(B)(ii)(IV); 42 U.S.C. 300g-1(b)(1)(B)(ii)(IV)).

[25] SDWA §1412(b)(1)(B)(i); 42 U.S.C. §300g-1(b)(1)(B)(i). Nothing in statute precludes EPA from modifying the list outside the five year timeline. See EPA, "Announcement of the Drinking Water Contaminant Candidate List," 63 *Federal Register* 10274, March 2, 1998, https://www.govinfo.gov/content/pkg/FR-1998-03-02/html/98-5313.htm.

[26] The 1978 Environmental Research, Development, and Demonstration Authorization Act (P.L. 95-477) directed EPA to establish the Science Advisory Board to provide scientific advice to the Administrator (42 U.S.C. §4365).

[27] EPA, "Drinking Water Contaminant Candidate List 3—Final," 74 *Federal Register* 51850, October 8, 2009. For more information on CCL 3, see EPA, "Contaminant Candidate List 3—CCL 3," https://www.epa.gov/ccl/contaminant-candidate-list-3-ccl-3.

[28] EPA, "Drinking Water Contaminant Candidate List 4—Final," 81 *Federal Register* 81101-81103, November 17, 2016. Discussion of the CCL 3 process is included in this *Federal Register* notice.

[29] EPA, "Drinking Water Contaminant Candidate List 4—Final," 81 *Federal Register* 81099, November 17, 2016. For more information on CCL 4, see EPA, "Contaminant Candidate List 4—CCL 4," https://www.epa.gov/ccl/contaminant-candidate-list-4-ccl-4-0.

[30] SDWA §1445(a)(2); 42 U.S.C. §300g-4(a)(2).

monitoring.[31] EPA uses data collected through UCMRs to estimate whether the occurrence of the contaminant in public water supplies is local, regional, or national in scope.

UCMRs set a minimum reporting level (MRL) for each contaminant. MRLs are not health based; rather, they establish concentrations for reporting and data collection purposes. EPA makes the UCMR monitoring results available to the public and reports the number of detections above the MRL and also detections above EPA's health-based reference levels (discussed below), where available. The act includes an authorization of appropriations to cover monitoring and related costs for small systems (serving 10,000 persons or fewer). However, large systems pay UCMR monitoring and laboratory costs.[32]

In 2012, EPA issued the third UCMR (UCMR 3), under which 4,864 public water systems tested their drinking water for six PFAS—including PFOA and PFOS—between January 2013 and December 2015.[33] Among these systems, EPA reported the following monitoring results for PFOA and PFOS:

- 117 of the public water systems reported detections of PFOA at levels above the MRL of 20 ppt, and
- 95 reported detections of PFOS at concentrations above the MRL of 40 ppt.[34]

Overall, 63 of the 4,864 (1.3%) water systems that conducted PFAS monitoring reported at least one sample with PFOA and/or PFOS (separately or combined) concentrations exceeding EPA's health advisory level of 70 ppt for PFOA and PFOS.[35] EPA estimates that these 63 water systems serve approximately 5.5 million individuals. Of the 63 systems:

- Nine reported detections of both PFOS and PFOA above 70 ppt;
- Four reported detections of PFOA above 70 ppt;
- 37 reported detections of PFOS above 70 ppt; and

---

[31] SDWA §1445(a)(2); 42 U.S.C. §300g-4(a)(2). EPA estimates that approximately 82% of the population receives water from public water systems that serve more than 10,000 individuals. Section 2021 of America's Water Infrastructure Act (P.L. 115-270) amended Section 1445 to require public water systems serving between 3,300 and 10,000 individuals to monitor for unregulated contaminants—subject to the availability of appropriations—to support costs associated with monitoring for these systems. This requirement enters into effect three years after the date of enactment of P.L. 115-270 (i.e., October 23, 2021).

[32] SDWA Section 1445(a)(2)(H)—Title 42, Section 300g-4(a)(2)(H) of the *United States Code*—authorizes appropriations of $10 million for each of FY2019-FY2021 for EPA to pay the reasonable costs of testing and laboratory analysis for small systems. Additionally, SDWA directs EPA to reserve $2 million from the Drinking Water State Revolving Fund appropriation to pay the costs of small system UCMR monitoring (SDWA §1452(o); 42 U.S.C. §300j-12(o)).

[33] EPA, "Revisions to the Unregulated Contaminant Monitoring Regulation (UCMR 3) for Public Water Systems: Final Rule," 77 *Federal Register* 26072-26101, May 2, 2012. This rule required monitoring for 29 unregulated contaminants. The PFAS for which monitoring was conducted include PFOA, PFOS, perfluorononanoic acid, perfluorohexanesulfonic acid, perfluoroheptanoic acid, and perfluorobutanesulfonic acid (PFBS).

[34] EPA, *Data Summary of the Third Unregulated Contaminant Monitoring Rule*, January 2017, p. 11, https://www.epa.gov/dwucmr/data-summary-third-unregulated-contaminant-monitoring-rule.

[35] Testimony of Peter Grevatt, Director, Office of Ground Water and Drinking Water, EPA, before the House Committee on Energy and Commerce, Subcommittee on Environment; hearing on *Perfluorinated Chemicals in the Environment: An Update on the Response to Contamination and Challenges Presented*, September 6, 2018. In May 2016, EPA issued non-enforceable health advisory levels for lifetime exposure, with a margin of safety, to PFOA and PFOS in drinking water. EPA established the Lifetime Health Advisory level for PFOA and PFOS at 70 ppt, separately or combined.

- 13 reported detections of PFOA and PFOS (combined but not separately) above 70 ppt. [36]

Systems with PFOA or PFOS detections above 70 ppt were located in 21 states, the Pima-Maricopa Indian community, and two U.S. territories.[37]

EPA's PFAS Action Plan notes that the agency intends to propose monitoring requirements for other PFAS when it proposes the next UCMR (UCMR 5) in 2020.[38] As of June 2019, EPA has developed an analytical method to detect 18 PFAS in drinking water supplies.[39] The plan states that the agency would use the monitoring data gathered through UCMR 5 to evaluate the national occurrence of additional PFAS.[40] The agency is currently working to develop analytical methods to support monitoring for additional PFAS.

Regulatory Determinations

SDWA requires EPA, every five years, to make a regulatory determination—a determination of whether or not to promulgate a national primary drinking water regulation—for at least five contaminants on the CCL.[41] To consider a contaminant for a regulatory determination (RD), EPA requires, at a minimum, a peer-reviewed risk assessment and nationally representative occurrence data. In selecting contaminants for an RD, SDWA requires EPA to give priority to those that present the greatest public health concern while considering a contaminant's health effects on specified subgroups of the population (e.g., infants, children, pregnant women) who may be at greater risk of adverse health effects due to exposure to a contaminant.[42]

As noted above, to make a positive determination to regulate a contaminant, EPA must find that (1) a contaminant may have an adverse health effect; (2) it is known to occur or there is a substantial likelihood that it will occur in public water systems with a frequency and at levels of public health concern; and (3) in the sole judgment of the EPA Administrator, regulation of the contaminant presents a meaningful opportunity for health risk reduction for persons served by water systems.[43] SDWA directs EPA to publish a preliminary determination and seek public comment prior to making an RD.[44] EPA may also make RDs for contaminants not listed on the CCL if EPA finds that the statutory criteria regarding health effects and occurrence are satisfied.[45]

---

[36] Email communication with EPA, May 30, 2019.

[37] Monitoring results for individual water systems (listed by state) are available on EPA's UCMR 3 website: https://www.epa.gov/dwucmr/third-unregulated-contaminant-monitoring-rule. This short report does not correlate levels of exposure based on individual served by these water systems.

[38] EPA did not require monitoring for any PFAS in UCMR 4.

[39] EPA, Determination of Selected Per- and Polyfluorinated Alkyl Substance in Drinking Water by Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry, November 2018, https://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=537290&Lab=NERL.

[40] EPA, *EPA's Per- and Polyfluoroalkyl Substances (PFAS) Action Plan*, February 14, 2019, p. 21, https://www.epa.gov/pfas/epas-pfas-action-plan.

[41] SDWA §1412(b)(1)(B)(ii); 42 U.S.C. 300g-1(b)(1)(B)(ii).

[42] SDWA §1412(b)(1)(C); 42 U.S.C. 300g-1(b)(1)(C).

[43] SDWA §1412(b)(1)(A); 42 U.S.C. §300g-1(b)(1)(A). The Administrator's determination whether or not to regulate a contaminant is not subject to judicial review (SDWA §1412(b)(1)(B)(ii)(IV); 42 U.S.C. 300g-1(b)(1)(B)(ii)(IV)).

[44] Section 1412(b)(1)(B)(ii); 42 U.S.C. 300g-1(b)(1)(B)(ii). The act authorizes EPA to promulgate an interim national primary drinking water regulation without making a regulatory determination or completing the other analyses to respond to an urgent threat to public health (SDWA §1412(b)(1)(D); 42 U.S.C. §300g-1).

[45] SDWA §1412(b)(1)(B)(ii)(III); 42 U.S.C. 300g-1(b)(1)(B)(ii)(III).

EPA has issued RDs for CCL 1 through CCL 3.[46] EPA published final determinations that no regulatory action was appropriate or necessary for nine contaminants on CCL 1 (2003) and 11 contaminants (including perchlorate) on CCL 2 (2008). In the most recent RD (2016), EPA determined that regulation was not needed for four of the 116 contaminants listed on CCL 3. EPA delayed a determination on a fifth contaminant, strontium, "in order to consider additional data and decide whether there is a meaningful opportunity for health risk reduction by regulating strontium in drinking water."[47]

In 2014, when EPA published preliminary RDs for contaminants on CCL 3 (including PFOA and PFOS), UCMR 3 monitoring was underway and national occurrence data were not available. EPA did not include any PFAS among the contaminants selected for the third RD. In November 2016, EPA included PFOA and PFOS on the agency's list of unregulated contaminants for which sufficient health effect and occurrence data were available to make RDs.[48]

The next round of RDs is scheduled for 2021, although SDWA does not prevent EPA from making determinations outside of that five-year cycle.[49] EPA states in the *Spring 2019 Unified Regulatory Agenda* that it plans to propose preliminary determinations for two PFAS—PFOA and PFOS—by the end of 2019 and make final determinations by the end of 2020.[50]

Developing Regulations and Standards for Emerging Contaminants

Once the Administrator makes a determination to regulate a contaminant, SDWA allows EPA 24 months to propose a "national primary drinking water regulation" and request public comment. EPA is required to promulgate a final rule within 18 months after the proposal.[51] SDWA authorizes EPA to extend the deadline to publish a final rule for up to nine months, by notice in the *Federal Register*.[52]

For each contaminant that EPA determines to regulate, EPA is required to establish a non-enforceable maximum contaminant level goal (MCLG) at a level at which no known or anticipated adverse health effects occur and which allows an adequate margin of safety.[53] An MCLG is based solely on health effects data and does not reflect cost or technical feasibility

---

[46] EPA, "Announcement of Regulatory Determinations for Priority Contaminants on the Contaminant Candidate List," 68 *Federal Register* 42898, July 18, 2003; EPA, "Drinking Water: Regulatory Determinations Regarding Contaminants on the Second Drinking Water Contaminant Candidate List—Preliminary Determinations," 72 *Federal Register* 24016, May 1, 2007; EPA, "Announcement of Final Regulatory Determinations for Contaminants on the Third Drinking Water Contaminant Candidate List," 81 *Federal Register* 18, January 4, 2016.

[47] EPA, "Announcement of Final Regulatory Determinations for Contaminants," 81 *Federal Register* 13, January 4, 2016, https://www.epa.gov/ccl/regulatory-determination-3.

[48] EPA, "Drinking Water Contaminant Candidate List 4—Final," 81 *Federal Register* 81102-81104, November 17, 2016. For more information on CCL 4, see EPA, "Contaminant Candidate List 4—CCL 4."

[49] For example, EPA made an out-of-cycle determination—reversing its 2008 decision—and published a determination to regulate perchlorate in 2011 between the second and third *Federal Register* notices of final RDs.

[50] For more information on *Spring 2019 Unified Regulatory Agenda*, see Office of Management and Budget, Office of Information and Regulatory Affairs, "Spring 2019 Unified Agenda of Regulatory and Deregulatory Actions," https://www.reginfo.gov/public/do/eAgendaMain.

[51] SDWA §1412(b)(3); 42 U.S.C. 300g-1(b)(3).

[52] SDWA §1412(b)(1)(E); 42 U.S.C. 300g-1(b)(1)(E).

[53] When developing regulations, EPA is required to (1) use the best available peer-reviewed science and supporting studies and data and (2) make publicly available a risk assessment document that discusses estimated risks, uncertainties, and studies used in the assessment. Concurrent with proposing a regulation, SDWA requires EPA to publish a "health risk reduction and cost analysis." SDWA §1412(b)(4)(A); 42 U.S.C. 300g-1(b)(4)(A).

considerations. EPA derives an MCLG based on an estimate of the amount of a contaminant that a person can be exposed to on a daily basis that is not anticipated to cause adverse health effects over a lifetime.[54] This amount is derived using the best available peer-reviewed studies and incorporates uncertainty factors to provide a margin of protection for sensitive subpopulations. In developing an MCLG, EPA also estimates the general population's exposure to a contaminant from drinking water and other sources (e.g., food, dust, soil, and air). After considering other exposure routes, EPA estimates the proportion of exposure attributable to drinking water (i.e., the relative source contribution). When exposure information is not available, EPA uses a default assumption that 20% of exposure to a contaminant is attributable to drinking water. EPA applies the relative source contribution to ensure that an individual's total exposure from all sources remains within the estimated protective level.[55]

The MCLG provides the basis for calculating a drinking water standard. Thus, EPA's ability to develop a drinking water regulation for a contaminant is dependent, in part, on the availability of peer-reviewed scientific studies.

Drinking water regulations generally specify a maximum contaminant level (MCL)—an enforceable limit for a contaminant in public water supplies.[56] SDWA requires EPA to set the MCL as close to the MCLG as feasible.[57] When assessing feasibility, the law directs EPA to consider the best available (and field-demonstrated) treatment technologies, taking cost into consideration.[58] Each regulation also establishes associated monitoring, treatment, and reporting requirements. These regulations can cover multiple contaminants and, generally, establish an MCL for each contaminant covered by the regulation.

Regulations generally take effect three years after promulgation. EPA may allow up to two additional years if the Administrator determines that more time is needed for public water systems to make capital improvements. (States have the same authority for individual water systems.[59]) The law directs EPA to review—and if necessary revise—each regulation every six years and requires that any revision maintain or provide greater health protection.[60]

Health Advisories

For emerging contaminants of concern, data may be limited, particularly regarding a contaminant's potential health effects and occurrence in public water supplies. SDWA authorizes EPA to issue health advisories for contaminants in drinking water that are not regulated under the act.[61] These advisories provide information on a contaminant's health effects, chemical

[54] EPA follows this process to evaluate non-carcinogenic effects. For carcinogens, EPA typically sets the MCLG at zero.

[55] EPA, *Drinking Water Health Advisory for Perfluorooctanoic Acid (PFOA)*, May 2016, p. 32, https://www.epa.gov/ground-water-and-drinking-water/supporting-documents-drinking-water-health-advisories-pfoa-and-pfos.

[56] SDWA does not prohibit states from setting stricter standards.

[57] SDWA §1412(b)(4)(B); 42 U.S.C. 300g-1(b)(4)(B). If the treatment of a contaminant is not feasible—technologically or economically—EPA may establish a treatment technique in lieu of an MCL (§1412(b)(7)(A); 42 U.S.C. 300g-1(b)(7)(A).

[58] SDWA §1412(b)(4)(D); 42 U.S.C. 300g-1(b)(4)(D).

[59] SDWA §1412(b)(10); 42 U.S.C. 300g-1(b)(10).

[60] SDWA §1412(b)(9); 42 U.S.C. 300g-1(b)(9).

[61] SDWA §1412(b)(1)(F); 42 U.S.C. §300g-1(b)(1)(F).

properties, occurrence, and exposure. They also provide technical guidance on identifying, measuring, and treating contaminants.

Health advisories include non-enforceable levels for concentrations of contaminants in drinking water. EPA sets health advisories at levels that are expected to protect the most sensitive subpopulations (e.g., nursing infants) from any deleterious health effects, with a margin of protection, over specific exposure durations (e.g., one-day, 10-day, or lifetime).[62] These non-regulatory levels are intended to help states, water suppliers, and others address contaminants for which federal (or state) drinking water standards have not been established. Some states may use health advisories to inform their own state-specific drinking water regulations.

Health advisories may be used to address various circumstances: to provide interim guidance while EPA evaluates a contaminant for possible regulation, to provide information for contaminants with limited or localized occurrence that may not warrant regulation, and to address short-term incidents or spills. EPA has issued health advisories for more than 200 contaminants to address different circumstances and subsequently established regulations for many of these contaminants.[63]

In May 2016, EPA issued non-enforceable health advisory levels for lifetime exposure to PFOA and PFOS in drinking water.[64] These replaced provisional advisories EPA issued in 2009 for PFOA (400 ppt) and PFOS (200 ppt).[65] EPA established the Lifetime Health Advisory level for PFOA and PFOS at 70 ppt, separately or combined.[66] In calculating the health advisory level, EPA applied a relative source contribution of 20% (i.e., an assumption that 20% of PFOS and/or PFOA exposure is attributable to drinking water and 80% is from diet, dust, air or other sources).[67] These levels are intended to protect the most sensitive subpopulations (e.g., nursing infants), with a margin of safety, over a lifetime of exposure.

Emergency Powers Orders

SDWA Section 1431 grants EPA "emergency powers" to issue orders to abate an imminent and substantial endangerment to public health from "a contaminant that is present in or is likely to enter a public water system or an underground source of drinking water" and if the appropriate state and local authorities have not acted to protect public health.[68] This authority is available to

---

[62] EPA, *2018 Edition of the Drinking Water Standards*, pp. 17-25.

[63] EPA, *Drinking Water Health Advisory for Perfluorooctanoic Acid (PFOA)*, p. 11. See also EPA, *2018 Edition of the Drinking Water Standards and Health Advisories Tables*, March 2018, https://www.epa.gov/sites/production/files/2018-03/documents/dwtable2018.pdf.

[64] EPA, "Fact Sheet: PFOA and PFOS Drinking Water Health Advisories," 2016, https://www.epa.gov/sites/production/files/2016-06/documents/drinkingwaterhealthadvisories_pfoa_pfos_updated_5.31.16.pdf.

[65] For more information on PFOA and PFOS provisional health advisories, see EPA, "Provisional Health Advisories for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS)," https://www.epa.gov/sites/production/files/2015-09/documents/pfoa-pfos-provisional.pdf.

[66] EPA, "Lifetime Health Advisories and Health Effects Documents for Perfluorooctanoic Acid and Perfluorooctane Sulfonate," 81 *Federal Register* 33250, May 25, 2016. The advisories and related documents are available at https://www.epa.gov/ground-water-and-drinking-water/drinking-water-health-advisories-pfoa-and-pfos.

[67] Also in May 2016, EPA released health effects support documents for these two PFAS, which summarize the scientific literature that EPA evaluated to establish these advisories. For the accompanying health effects documents for PFOA and PFOS, see EPA, "Supporting Documents for Drinking Water Health Advisories for PFOA and PFOS," https://www.epa.gov/ground-water-and-drinking-water/supporting-documents-drinking-water-health-advisories-pfoa-and-pfos.

[68] 42 U.S.C. §300i.

address both regulated and unregulated contaminants. The EPA Administrator "may take such actions as he may deem necessary" to protect the health of persons who may be affected. Actions may include issuing orders requiring persons who caused or contributed to the endangerment to provide alternative water supplies or to treat contamination. When using this authority, EPA generally coordinates closely with states.

EPA reports that it has used its emergency powers under Section 1431 to require responses to PFOA and/or PFOS releases and related contamination of drinking water supplies at four sites, three of which involved the Department of Defense (DOD).[69]

- *Warminster Naval Warfare Center, Pennsylvania.* In 2014, EPA issued an administrative enforcement order directing the U.S. Navy to address PFOS in three drinking water supply wells at and near this National Priorities List site.[70]
- *Former Pease Air Force Base, New Hampshire.* In August 2015, EPA issued an administrative enforcement order to require the U.S. Air Force to design and construct a system to treat water systems contaminated from releases of PFOA and PFOS at the former Pease Air Force Base in New Hampshire.
- *Horsham Air Guard Station/Willow Grove, Pennsylvania.* In 2015, EPA issued an order directing the Air Guard/Air Force to treat onsite drinking water wells and to provide treatment for private offsite wells.
- *Chemours Washington Works Facility, West Virginia/Ohio.* EPA issued three emergency orders to this facility in 2002, 2006, and 2009—and amended the 2009 order in 2017 to incorporate the 2016 Lifetime Health Advisory level—requiring DuPont and Chemours to offer water treatment, connection to a public water system, or bottled water where PFOA concentrations exceeded 70 ppt.

MCLs and Remedial Actions

Under CERCLA (or "Superfund"), MCLs may be considered in selecting remedial actions for releases of hazardous substances, pollutants, and other contaminants. However, CERCLA establishes liability only for releases of hazardous substances. No PFAS is designated as a hazardous substance (42 U.S.C. 9621(d)).

As announced in its PFAS Action Plan, EPA proposed guidance in April 2019 for PFOA and PFOS groundwater screening levels and preliminary remediation goals for evaluating potential risks at sites under CERCLA and sites subject to corrective action under the Resource Conservation and Recovery Act. EPA proposed PFOA and PFOS screening levels of 40 ppt and preliminary remediation goals of 70 ppt (EPA's Lifetime Health Advisory level). This guidance would supplement existing CERCLA guidance, which EPA uses to assess risks and inform the selection of site-specific response actions.

[69] EPA, *EPA's Per- and Polyfluoroalkyl Substances (PFAS) Action Plan*, pp. 55-56. In April 2019, EPA responded to CRS listing specific federal and state enforcement actions taken to address PFAS under various statutory authorities. These actions include the four examples of the use of SDWA Section 1431 emergency powers and orders under the authority of TSCA and the Resource Conservation and Recovery Act. According to EPA's Enforcement and Compliance History Online tool, which identifies enforcement actions since 2009, EPA has issued 119 orders using the SDWA Section 1431 authority to respond to imminent and substantial endangerment as of May 2019. Of the 119 orders, EPA issued 113 orders to public water systems for a variety of circumstances, including corrosive pipes, discovery of disease vectors in finished water storage, and MCL violations, among others.

[70] CERCLA directs EPA to maintain a National Priorities List to identify the most hazardous sites for the purpose of prioritizing cleanup actions.

PFAS Legislation in the 116th Congress

For several years, congressional attention has focused on whether or not EPA might set drinking water standards for PFOA, PFOS, or other PFAS. The conference report accompanying the Consolidated Appropriations Act, 2019 (P.L. 116-6, enacted February 15, 2019), directed EPA to brief specific committees within 60 days of enactment (i.e., April 16, 2019) on the agency's plans to evaluate the need for an MCL for PFAS.[71] On June 27, 2019, the Senate passed a substitute amendment to S. 1790, the National Defense Authorization Act (NDAA) for Fiscal Year 2020 (S.Amdt. 764). Among multiple other PFAS provisions, this legislation, as discussed below, would direct EPA to set drinking water standards for PFOA, PFOS, and potentially other PFAS.

Members in the 116th Congress have introduced more than 35 bills to address PFAS through a range of actions and federal agencies. The intent of many of these bills is to reduce exposures to PFAS in drinking water and to prevent or remediate the contamination of groundwater and drinking water by these substances. These bills continue efforts from the 115th Congress that included the enactment of the Agriculture Improvement Act of 2018—known as the 2018 farm bill (P.L. 115-334)—which contained several provisions to address PFAS contamination in drinking water of rural communities.[72]

This discussion focuses on legislation that would amend SDWA or otherwise directly affect public water systems. **Table 1** includes drinking-water-related bills offered in the 116th Congress. Among these, S. 1473 and H.R. 2377 would direct EPA to establish an MCL for PFAS. H.R. 2800 would expand monitoring for PFAS in drinking water. Several bills—including H.R. 2741 S. 611, H.R. 1417, H.R. 2533, and H.R. 2570—would authorize grants for water systems and/or households to treat PFAS in drinking water.

The House-reported and Senate-passed versions of the NDAA for FY2020 (S. 1790, as amended, and H.R. 2500) contain various PFAS provisions specific to DOD, some paralleling free-standing bills (e.g., H.R. 2626 and S. 1372). The Senate-passed bill would address PFAS through multiple federal agencies and authorities. Amending SDWA, Title LXVII, Subtitle B, of the Senate bill would require EPA to promulgate regulations for certain PFAS, authorize states to use their Drinking Water State Revolving Funds (DWSRF) to provide grants to public water systems for PFAS treatment, and require monitoring for additional PFAS as analytical methods become available.

Other subtitles of Title LXVII of the Senate-passed NDAA broadly parallel several other PFAS-related bills. Subtitle A would amend the Emergency Planning and Community Right-to-Know

---

[71] U.S. Congress, House of Representatives, Conference Committee, Conference Report to Accompany H.J.Res. 31, Making Further Continuing Appropriations for the Department of Homeland Security for Fiscal Year 2019, and for Other Purposes, committee print, 116th Cong., 1st sess., February 13, 2019, H.Rept. 116-9, (Washington: GPO, 2019), p. 741.

[72] P.L. 115-334 includes several provisions to address PFAS in rural communities' drinking water. Section 6404 expands an existing program to authorize qualified nonprofit entities to provide technical assistance to rural communities to address contamination of drinking water and surface water supplies by emerging contaminants, including PFAS (7 U.S.C. §1926(a)(14)). Section 6409 of the 2018 farm bill authorizes loans and grants for installation of water treatment to address ground well water contamination at individual households (7 U.S.C. §1926e). Section 6407(a) authorizes the use of U.S. Department of Agriculture (USDA) Emergency Water Assistance grants to address contamination that poses human health or environmental risks and was caused by circumstances beyond the control of the applicant (7 U.S.C. §1926a). Additionally, Section 6407(b) directs USDA to coordinate an interagency task force on drinking water in rural communities located near military bases. For more information on these programs, see CRS Report RL30478, *Federally Supported Water Supply and Wastewater Treatment Programs*, coordinated by Jonathan L. Ramseur.

Act of 1986 to direct EPA to list certain PFAS on the Toxics Release Inventory. Subtitle C would direct the U.S. Geological Survey to conduct nationwide sampling for PFAS in water and soil. Subtitle D would require federal agencies to coordinate PFAS research and direct EPA to develop a technical assistance program to states with respect to emerging contaminants in drinking water. Subtitle E includes provisions that would address PFAS under TSCA and would require EPA to publish guidance on PFAS disposal.

As noted, several bills would direct EPA to issue drinking water regulations for specific PFAS or all PFAS. Prior Congresses have directed EPA to regulate specific contaminants in drinking water in lieu of following the act's contaminant assessment and selection process.[73] This approach has been used to prompt EPA to act on specific contaminants of concern and/or to specify a deadline for issuing regulations under development. In the case of PFAS, representatives of public water systems and others have cautioned against bypassing a science-based and risk-driven process.[74] As regulatory compliance costs are borne by communities, water utilities have urged that regulations be based on sound science to better ensure risk reduction benefits.[75] Others are urging federal leadership to provide more certainty to states and communities with water supplies.[76] State drinking water regulators have noted that some states may lack the resources or authority to assess and regulate drinking water contaminants, including PFAS. A further concern is that state-by-state actions could create public confusion regarding the safety of drinking water.[77]

Table 1. Legislation to Address PFAS in Drinking Water in the 116th Congress

Bill Number, Most Recent Action	Short Title (If Provided)	SDWA § Amended	Key Provisions/Notes
H.R. 1417 and S. 611 Introduced, February 28, 2019 (See companion bill, S. 611)	Water Affordability, Transparency, Equity, and Reliability Act of 2019	§1452(k)(1)	Would authorize states to use a portion of their DWSRF annual grants to provide assistance to community water systems, and households with wells, to treat PFAS contamination in drinking water.
H.R. 2377 Introduced, April 29, 2019	Protect Drinking Water from PFAS Act	§1412(b)(12)	Would require EPA to publish an MCL goal and promulgate a national primary drinking water regulation for total PFAS.
H.R. 2533 Introduced, May 7, 2019	Providing Financial Assistance for Safe Drinking Water Act	Adds §1459E	Would establish a grant program for community water systems' capital infrastructure to treat PFAS contamination. Would authorize appropriations of $500 million to support the grant program.
H.R. 2570 Introduced, May 8, 2019	PFAS User Fee Act of 2019	N/A	Would direct EPA to establish a fee to manufacture PFAS, would establish a grant program for community water systems and publicly owned treatment works for operations and maintenance cost of PFAS removal.

[73] For example, in the Safe Drinking Water Amendments of 1996 (P.L. 104-182), the 104th Congress directed EPA to regulate radon, propose a new arsenic standard, and evaluate sulfate for regulation (SDWA §1412(b)(12); 42 U.S.C. 300g(b)(12); SDWA §1412(b)(13); 42 U.S.C. 300g(b)(13)).

[74] See, for example, testimony of Mehan.

[75] See, for example, testimony of Mehan.

[76] See for example, testimony of Daniels.

[77] Association of State Drinking Water Administrators, comment letter to EPA on draft human health toxicity assessments for GenX chemicals and PFBS, EPA Docket No. #EPA-HQ-OW-2018-0614, January 22, 2019.

Bill Number, Most Recent Action	Short Title (If Provided)	SDWA § Amended	Key Provisions/Notes
H.R. 2741 Introduced, May 15, 2019 (Title II contains the same provisions as H.R. 2533)	Leading Infrastructure for Tomorrow's America Act	Adds §1459E	Would establish a grant program for community water systems' capital infrastructure to treat PFAS contamination. Would authorize appropriations of $500 million to support the grant program.
H.R. 2800 Introduced, May 16, 2019	PFAS Monitoring Act of 2019	Adds §1445(k)	Would require public water systems to monitor for 30 PFAS initially, increasing to all PFAS in two years.
S. 1251 Introduced, April 30, 2019	Safe Drinking Water Assistance Act of 2019	N/A	Would direct EPA to coordinate federal efforts related to emerging contaminants, among other provisions.
S. 1473 Introduced, May 15, 2019	Protect Drinking Water from PFAS Act of 2019	§1412(b)(12)	Would require EPA to publish an MCL goal and promulgate a national primary drinking water regulation for total PFAS.
S. 1507 Reported, amended, June 19, 2019	PFAS Release Disclosure Act	§1412(b)(2), §1452	Would direct EPA to (1) issue MCLs for PFAS (PFOA and PFOA at a minimum) within two years of enactment, (2) require monitoring for all PFAS with validated test methods in UCMR 5, and (3) issue more PFAS health advisories. It would authorize states to use DWSRFs for grants for public water systems to address PFAS and would authorize appropriations for that purpose. As reported, this bill parallels S.Amdt. 764.
Subtitle B of Title LXVII of the modified amendment S.Amdt. 764, in the nature of a substitute to S. 1790 Passed by the Senate June 27, 2019 (see also S. 1507, as reported)	To Amend National Defense Authorization Act for Fiscal Year 2020	§1412(b)(2), §1452	Would direct EPA to (1) issue MCLs for PFOS and PFOA and potentially other PFAS within two years of enactment, (2) require monitoring for all PFAS with validated test methods in UCMR 5, and (3) issue more PFAS health advisories. It would authorize states to use DWSRFs for grants for public water systems to address PFAS and would authorize appropriations for that purpose.

Source: Compiled by CRS from Congress.gov.

Notes: The bills included in the table are those that are related to drinking water. Other bills have been introduced for other purposes.

Several bills would address PFAS at U.S. military installations, create a registry of veterans who may have been exposed to PFAS, or require labeling of food packaging manufactured with PFAS, among other purposes. Many of the bills listed below were offered as amendments to S. 1790. Listed below are bills that would amend other environmental statutes or take other environmental actions to address PFAS contamination of water resources:

- H.R. 535 and S. 638 would require EPA to designate all PFAS as hazardous substances under CERCLA. Such designations would establish cleanup liability for releases of PFAS into the environment and create reporting requirements for such releases.

- H.R. 1976 and S. 950 would direct the U.S. Geological Survey to carry out nationwide sampling of water and soil for PFAS and establish a performance standard for detecting multiple PFAS in water, among other provisions.
- H.R. 2500 (the FY2020 NDAA bill) would reauthorize appropriations to support a study on the health implications of PFAS in drinking water for the Agency of Toxic Substances and Disease Registry; require the Navy to publish military specifications for a fluorine-free fire-fighting agent by January 1, 2025; prohibit the use of any aqueous film-forming foam on U.S. military installations on or after September 30, 2029; and prohibit non-emergency and training uses of aqueous film-forming foam at U.S. military installations; among other purposes.
- H.R. 2591 would amend the Solid Waste Disposal Act to require EPA to promulgate regulations that prohibit the incineration of PFAS-containing fire-fighting foam, among other purposes.
- Several bills (e.g., H.R. 2596, H.R. 2600, and H.R. 2608) would amend TSCA to require EPA to further regulate PFAS in commerce, among other purposes.
- H.R. 2605 would direct EPA to list PFAS as hazardous air pollutants under the Clean Air Act.
- H.R. 2626 and S. 1372 would encourage federal agencies to enter into cooperative agreements with states for the removal or remediation of PFAS contamination from water and soil.
- S. 1507, as reported, broadly parallels a substitute amendment to S. 1790, the National Defense Authorization Act for FY2020 (S.Amdt. 764).
- In addition to the non-DOD related PFAS provisions described above, the Senate-passed substitute amendment to S. 1790 would direct DOD to enter into a cooperative agreement with states to address PFAS testing, monitoring, removal, and remedial actions for drinking, surface, or ground water; reauthorize appropriations to support a study on PFAS contamination in drinking water for the Agency for Toxic Substances and Disease Registry; prohibit DOD after October 1, 2022, from procuring fire-fighting foam, which contains more than 1 part per billion of PFAS; and authorize DOD environmental restoration activities on real property leased to or operated by a state for National Guard training. Among other provisions, this bill would also require DOD to cease using PFAS fire-fighting foam and dispose of existing stocks not later than October 1, 2023.

Appendix. Selected EPA Drinking-Water-Related Actions

Table A-1. Selected Drinking-Water-Related Actions in EPA's PFAS Action Plan

Action	Description	Timeframe
Provisional Health Advisories	Developed provisional health advisory values for short-term exposure to PFOA and PFOS at 400 ppt and 200 ppt, respectively	Completed January 2009
Analytical Method Development	Developed an analytical method (Method 537) for measuring PFOA, PFOS, and 12 other PFAS in drinking water	Completed September 2009
Contaminant Candidate List 3	Included PFOS and PFOA on the third contaminant candidate list	Completed October 2009
Unregulated Contaminant Monitoring Rule 3	Monitored for unregulated contaminants, including six PFAS in public water supplies using analytical methods developed by EPA	Completed between 2013 and 2015
Lifetime Health Advisories for PFOA and PFOS	Developed Health Advisories for PFOA and PFOS that identify non-enforceable levels at which or below adverse health effects are not anticipated to occur	Completed May 2016
Contaminant Candidate List 4	Included PFOS and PFOA on the fourth contaminant candidate list	Completed November 2016
Analytical Method Development	Expanded Method 537 to Method 537.1, which measures four short-chain PFAS, including GenX compounds[a]	Completed November 2018
Water Contaminant Information Tool: Profiles for PFOA and PFOS	Developed contaminant profiles for PFOA and PFOS for EPA's Water Contaminant Information Tool, which is used by the water sector to prepare for, respond to, or recover from drinking water incidents	Completed December 2018
Point-of-Entry and Point-of-Use Home Treatment Systems	Evaluated commercially available reverse osmosis and granular activated carbon units that can serve households through point-of-use or point-of-entry treatment applications for PFAS	Completed October 2018
Treatability Cost Models	Update Drinking Water PFAS Treatability cost models	Ongoing

Drinking Water Treatability Database	Update Drinking Water Treatability Database for effective drinking water treatment processes for PFOA, PFOS, and additional PFAS	Ongoing
Research for Drinking Water Treatment	Conduct experiments to evaluate performance and cost (capital and maintenance operations) of treatment and potential unintended effects of using specific technologies; test granular activated carbon and ion exchange treatment technologies	Anticipated Fall 2019
Regulatory Determination 4	Propose a regulatory determination for PFOA and PFOS	Anticipated December 2019[b]
Analytical Method Development	Develop new validated analytical method for short-chain PFAS, which are currently not measured by the Method 537 or Method 537.1	Anticipated 2019
Unregulated Contaminant Monitoring Rule 5	Develop unregulated contaminant monitoring rule for additional PFAS using the new validated analytical method to detect more PFAS at lower concentrations	Anticipated 2020-2025

Source: Compiled by CRS from EPA's PFAS Action Plan.

Notes: This table includes only EPA's actions directly related to drinking water. The Action Plan includes other EPA efforts to address PFAS under other environmental statutes.

a. GenX is a chemical process used to create fluoropolymers.

b. As stated in the *Spring 2019 Unified Regulatory Agenda*, EPA plans to make final regulatory determination for PFOA and PFOS in December 2020.

Author Contact Information

Elena H. Humphreys
Analyst in Environmental Policy
#redacted#@crs.loc.gov , 7-....

Mary Tiemann
Specialist in Environmental Policy
#redacted#@crs.loc.gov 7-....

EXHIBIT

C-139

November 19, 2019

The Honorable Frank Pallone
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Greg Walden
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Pallone and Ranking Member Walden:

We, the undersigned associations, write to you in opposition to H.R. 535, the "PFAS Action Act of 2019," as well as the amendment offered in the nature of a substitute to H.R. 535.

PFAS are a large and diverse group of chemicals with unique properties that have been used in a broad number of beneficial applications for years. Heightened attention to potential health effects of certain PFAS has led to an increased public concern and interest in new regulatory protections in this area.

We understand these concerns and are committed to working with legislators, regulators, and all stakeholders to establish risk-based standards that protect human health and the environment. We also support the development of a consistent approach and clear timelines for assessing and regulating specific PFAS across all relevant federal agencies to ensure that government regulations, actions, and communications are coordinated for maximum effectiveness.

Any federal action should not address PFAS as a class, be based on sound science and the weight of the scientific evidence, and not predetermined outcomes. Further, Congress should not circumvent existing regulatory authorities. EPA, as well as other relevant agencies, should retain their traditional power to study PFAS and determine whether to regulate certain PFAS.

We look forward to working with you on this important matter as the legislative process continues.

Sincerely,

U.S. Chamber of Commerce
AdvaMed
Airlines for America
Airports Council International – North America
Alliance of Automobile Manufacturers
American Chemistry Council
American Coatings Association
American Forest & Paper Association
American Fuel & Petrochemical Manufacturers
American Petroleum Institute
Associated General Contractors of America
Council of Industrial Boiler Owners
Flexible Packaging Association
International Liquid Terminals Association
National Association of Chemical Distributors
National Association of Manufacturers
SGIA – Specialty Graphics Imaging Association
Single Ply Roofing Industry

cc: Members of the Committee on Energy and Commerce

EXHIBIT

C-140

January 8, 2020

TO THE MEMBERS OF THE U.S. HOUSE OF REPRESENTATIVES:

PFAS are a large and diverse group of chemicals with unique properties that have been used in a broad number of beneficial applications for years. Heightened attention to potential health effects of certain PFAS has led to an increased public concern and interest in new regulatory protections in this area.

We understand these concerns and are committed to working with legislators, regulators, and all stakeholders to establish risk-based standards that protect human health and the environment. We also support the development of a consistent approach and clear timelines for assessing and regulating specific PFAS across all relevant federal agencies to ensure that government regulations, actions, and communications are coordinated for maximum effectiveness.

Any federal action should not address PFAS as a class or with predetermined outcomes, but rather should be based on sound science and the weight of the scientific evidence. Further, Congress should not circumvent existing regulatory authorities. The Environmental Protection Agency, as well as other relevant agencies, should retain their traditional power to study PFAS and determine whether to regulate certain PFAS. Many provisions included in the National Defense Authorization Act for Fiscal Year 2020, signed into law at the end of last year, took important steps towards meeting those goals.

We look forward to working with you on this important matter as the legislative process continues. We oppose H.R. 535, the "PFAS Action Act of 2019."

Sincerely,

U.S. Chamber of Commerce
Advamed
Airlines for America
American Chemistry Council
American Coatings Association
American Forest & Paper Association
American Fuel & Petrochemical Manufacturers
American Petroleum Institute
Associated General Contractors of America
Flexible Packaging Association
Foodservice Packaging Institute
International Liquid Terminals Association
National Association of Chemical Distributors
National Association of Manufacturers
National Cattlemen's Beef Association
Plastics Industry Association (PLASTICS)
Single Ply Roofing Industry
Society of Chemical Manufacturers and Affiliates
Specialty Graphic Imaging Association
TRSA – The Linen, Uniform and Facility Services Association

EXHIBIT

C-141

CHAMBER OF COMMERCE
OF THE
UNITED STATES OF AMERICA

NEIL L. BRADLEY
EXECUTIVE VICE PRESIDENT &
CHIEF POLICY OFFICER

1615 H STREET, NW
WASHINGTON, DC 20062
(202) 463-5310

March 26, 2019

The Honorable John Barrasso
Chairman
Committee on Environment
and Public Works
United States Senate
Washington, D.C. 20510

The Honorable Tom Carper
Ranking Member
Committee on Environment
and Public Works
United States Senate
Washington, D.C. 20510

Dear Chairman Barrasso and Ranking Member Carper:

The U.S. Chamber of Commerce thanks you for holding the hearing, "Examining the Federal Response to the Risks Associated with Per- and Polyfluoroalkyl Substances (PFAS)."

PFAS are a large and diverse class of chemicals with unique properties that have been used in a broad number of beneficial applications for many years. Heightened attention to potential health effects of certain PFAS compounds has understandably led to increased public concern and interest in new regulatory protections in this area.

The U.S. Chamber supports action to address these concerns, and is committed to proactively working with legislators, regulators, and all stakeholders to establish risk-based standards that protect human health and the environment. We believe collaboration and transparency are critical to any such efforts, and the government, industry, and the scientific community must work together to share knowledge and focus resources on the highest priorities based on actual risk, while utilizing existing regulatory processes to proactively address both current and future issues.

There are more than 4,000 PFAS class chemicals. The chemistries among these chemicals vary substantially and have different characteristics, profiles, and uses. Any federal action – legislation and regulation – should be undertaken on an individual chemical basis, rather than as a class. We also believe that science should guide decisions and neither legislation nor regulation should predetermine outcomes.

We also encourage the development of a consistent approach and clear timelines for assessing and regulating specific PFAS across all relevant federal agencies to ensure that government regulations, actions, and communications are consistent and coordinated for maximum effectiveness. Further, federal agencies should prioritize clear, science-based risk communication and regulatory transparency to ensure that the American public can better understand the actual risks associated with specific PFAS compounds.

We look forward to working with you on this important matter.

Sincerely,

Neil L. Bradley

cc: Members of the Senate Committee on Environment and Public Works

EXHIBIT

C-142

Scientific Studies

A decade ago, the FluoroCouncil members committed to the 2010/2015 Perfluorooctanoic Acid (PFOA) Stewardship Program, a global partnership between the U.S. Environmental Protection Agency and industry, based on voluntary corporate goals to reduce human and environmental exposure to PFOA and related long-chain fluorinated substances. This Program led to the virtual elimination of PFOA and related long-chain fluorinated substances, including long-chain fluorotelomer-based products, from facility emissions and product content of the participating companies. To continue to meet the critical performance properties provided by the long-chain fluorotelomer-based products, FluoroCouncil member companies developed alternatives, including short-chain fluorotelomer-based products with improved environmental and health profiles.

These short-chain fluorotelomer-based products have been well-studied by the scientific community, including scientists from academia, industry, and governmental agencies. Data have also been developed and provided to regulators as part of international chemical review processes. Much of the scientific research has focused on the impact of short-chain fluorotelomer-based products on human health and the environment.

Based on this research, the short-chain fluorotelomer-based products manufactured by FluoroCouncil members do not meet criteria for chemicals of concern based on their environmental fate and potential for adverse health effects (Stockholm Convention Criteria, European REACH PBT Criteria). In addition, the materials used to produce these products (manufacturing intermediates) and the degradation products formed as these materials break down in the environment do not meet these criteria.

Summaries of the environmental fate and health risk data associated with several key short-chain fluorotelomer substances are linked below. These summaries are based on reviews of available data conducted in 2014 and updated in December 2016.

- Commercial Products
- Manufacturing Intermediates
- Degradation Product

In addition to published data provided at the above links, FluoroCouncil member companies that have unpublished data on short-chain substances provide that data on their respective websites:

- AGC Inc.
- Daikin Industries, Ltd.

EXHIBIT

C-143

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

IN RE: AQUEOUS FILM-FORMING FOAMS PRODUCTS LIABILITY LITIGATION	MDL No. 2:18-mn-2873-RMG

PLAINTIFFS' MOTION FOR PROTECTIVE ORDER REGARDING DEFENDANTS' THIRD PARTY SUBPOENA TO WEST VIRGINIA UNIVERSITY

Plaintiffs, by and through Counsel, respectfully move for a protective order under Fed. R. Civ. P. 45 or, in the alternative, Fed. R. Civ. P. 26 directed to the April 6, 2020, third-party subpoena served by Defendants' Co-Lead Counsel on the West Virginia University Robert C. Byrd Health Sciences Center ("WVU"). Through their subpoena, Defendants improperly attempt to compel WVU to produce highly confidential and protected data collected, and work performed, through the C8 Health Project and by the C8 Science Panel, in flagrant violation of multiple orders entered by the West Virginia Circuit Court of Wood County in *Leach v. E. I. du Pont de Nemours & Co.*, No. 01-C-608, which shield such data from discovery.

To emphasize just how important it was to the *Leach* court and parties to protect the integrity of this highly confidential data, including personal medical information from tens of thousands of *Leach* class members, the *Leach* Court dictated that even an attempt to subpoena this data improperly, as done here by the Defendants, would be treated as contempt of court. Defendants have all been on notice of these orders and their requirements for many years (over a decade in some cases), as all the orders have been part of open, public court records, yet are now trying to use these current MDL proceedings as a convenient means to circumvent and totally

undermine those existing court orders. This Court should not allow Defendants to misuse and manipulate this Court's proceedings for such clearly improper and inappropriate purposes.

BACKGROUND

On April 6, 2020, Defense Co-Lead Counsel, on behalf of all the Defendants notified this Court that they intend to serve a subpoena on WVU. ("Subpoena") (attached as Ex. A). The Subpoena commanded WVU to make the following information available to Defendants at the office of WVU's Office of General Counsel on May 4, 2020 at 10 am:

> 1. Filed Data regarding any and all C8 Science Panel Studies overseen and/or conducted by the C8 Science Panel.
>
> 2. Documents and communications collected and/or evaluated by the C8 Science Panel relating to any C8 Science Panel Probable Link Assessment.
>
> 3. Filed Data regarding C8 Class Members' self-reported anthropometric measurements, blood samples, and medical charts/records and pathology reports from health care providers.
>
> 4. Filed Data regarding C8 Health Surveys, including C8 Class Members' demographic data; current and historical residential and employment information, including water source and use; personal medical diagnoses, treatments including medications, and physical symptoms; family medical history; pregnancy history and pregnancy-related outcomes for women; information about lifestyle and health behaviors; height; weight; and blood pressure.
>
> 5. Filed Data regarding C8 Health Project clinical laboratory tests conducted through LabCorp, Inc. in Burlington, North Carolina, including serum lipid; immune and inflammatory markers; liver, kidney, and thyroid function; complete blood count; serum electrolytes and protein; and endocrine function, including insulin and glucose.
>
> 6. Filed Data regarding C8 Health Project PFAS analyses, evaluations, procedures, and/or tests, including without limitation PFAS analyses through Exygen Research Inc., State College, Pennsylvania and AXYS Analytical Services Ltd., Sidney, British Columbia.
>
> 7. Any analyses, reports, evaluations, summaries, compendiums, charts, and/or models of Filed Data, including but not limited to any aggregate sets and/or collections of Filed Data.

> 8. Documents and communications regarding all draft and final articles or studies written, produced, conducted, or overseen by the C8 Science Panel, including the drafts of the articles and communications with peer reviewers and documents relating to peer review comments or feedback.

(Subpoena at 9-10.)

To help illustrate for the Court how egregious and improper it is for Defendants to try to subpoena this information, Plaintiffs offer the following brief summary of the relevant background regarding where this data originated, how and why it is "off-limits" to Defendants, and how this is just the latest attempt by certain defendants – namely the DuPont Entities - to try to gain access to this protected Science Panel data and find ways to undermine or malign its findings over the past seven years.

Both the C8 Health Project and the C8 Science Panel processes have their origins in the class action that was filed against DuPont in 2001 on behalf of certain Mid-Ohio Valley residents whose drinking water had been contaminated with PFOA (also known as "C8") released by DuPont, *Leach v. E. I. du Pont de Nemours & Co.*, No. 01-C-698 (Wood Cty. W. Va. Cir. Ct.).[1] After three years of litigation, including three issues taken to the West Virginia Supreme Court of Appeals, the parties eventually reached a class-wide settlement of the litigation through a complex written settlement agreement (the "Settlement") approved by the *Leach* court in 2005. In addition to terms providing for immediate clean water for the class, the Settlement also memorialized the parties' agreement to create, fund, and implement certain unique and innovative mechanisms for addressing and resolving class claims related to the impact of PFOA contamination on the class members' health.

[1] *See also In re E. I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 314 F. Supp. 3d 868, 869-71 (S.D. Ohio 2014) (discussing history of the *Leach* case).

At the time of the Settlement, the parties vigorously disputed the likelihood of adverse health impacts of PFOA among class members. Although DuPont had never disputed that PFOA could be capable of causing harm to humans at *some* level of exposure, DuPont still disputed that the level of PFOA in the drinking water of the actual *Leach* class members was sufficient to cause harm. Avoiding the uncertainties of a lay jury, the parties jointly agreed to remove this critical, yet common general causation issue from the on-going litigation process and submit the question of whether PFOA, at the level actually present in the drinking water of the *Leach* Class, was likely to be capable of causing serious disease among those class members to a new, jointly-selected independent panel of three epidemiologists (the "C8 Science Panel") who would resolve the issue for the whole class according to the specific criteria defined by the parties in the Settlement. The parties further agreed that the C8 Science Panel's independent decision on this general causation issue would be final and binding on the parties with respect to any further litigation between the parties.

To insure that the C8 Science Panel focused on the capacity of PFOA to be likely to cause adverse health effects to the *Leach* class members at the PFOA levels actually present in that class, the parties charged the C8 Science Panel, *not* with pursuing the traditional epidemiologist's charge of assessing whether a chemical is generally capable of causing harm at some yet undetermined level in the general population, but with assessing the extent of any "Probable Links" with PFOA among the *Leach* class. The parties specially defined a "Probable Link" to mean "it is *more likely than not* that there is a link between exposure to [PFOA] and a particular Human Disease among Class Members." *In re C*-8, 314 F. Supp. 3d at 870 (citing Settlement). The parties further agreed that, until the C8 Science Panel completed its work – in the form of "Probable Link" "Findings", all *Leach* class members would be barred from further litigating their health claims.

The parties also agreed that, once the C8 Science Panel released its final "Probable Link" Findings, the only health-related claims that class members could pursue would be those related to diseases for which the C8 Science Panel found a "Probable Link." All other health-based claims of the *Leach* class members relating to PFOA exposure would be released, "forever barred," and dismissed with prejudice.

As to its methods, the parties agreed that the C8 Science Panel was to select its own "objective criteria" and "protocols" to evaluate all the available evidence, when assessing Probable Links, which could include reviews of multiple studies and varying levels of exposure. The Panel would then submit a single, ultimate "Finding" and conclusion as to "whether such evidence demonstrates a Probable Link" with respect to a specific human disease, or not, for the class.

To assist the C8 Science Panel in assessing all available data, the *Leach* court also approved the creation and funding of the "C8 Health Project" as part of the final class-wide Settlement in 2005. Through the C8 Health Project, $70 million in Settlement funds was used to collect blood samples and basic medical information from approximately 69,000 *Leach* class members, based on assurances made to such class members that their personal, identifiable medical information and other personal data would be fully protected, kept strictly confidential, and never made available to DuPont or other third parties without their express approval and consent.

The C8 Science Panel ultimately undertook an unprecedented, comprehensive review of all the relevant, existing health data and studies, including an analysis of the health records and blood samples collected through the C8 Health Project, and even designed and implemented over a dozen of its own new studies into the health effects of PFOA on class members. As part of its overall study protocol, the C8 Science Panel reviewed and evaluated data from myriad individual studies and data sources before reaching a conclusion on any "Probable Links." Some of these

individual studies referred internally to associations with diseases at certain PFOA levels, while others suggested no such association, or indicated an association but at different PFOA levels. The C8 Science Panel carefully weighed and evaluated *all* of these individual studies and data according to the objective criteria the Panel itself selected for that purpose, and issued final written "Findings" in 2011 and 2012 as to whether *all* of the studies and data had persuaded the Panel that there either was a "Probable Link" or "No Probable Link" with particular diseases among class members and PFOA. The C8 Science Panel ultimately issued written final "Findings" that a Probable link existed for the following diseases: kidney cancer; testicular cancer; thyroid disease; ulcerative colitis; hypercholesterolemia; and pregnancy induced hypertension and preeclampsia.

Once the final Probable Link Findings were issued, *Leach* class members were permitted to bring individual claims against DuPont for these injuries. Ultimately, over 3,500 such cases were filed, which were consolidated in the Southern District of Ohio in the *In re C-8* MDL, No. 2:13-md-2433, overseen by Judge Sargus. After four years of litigation and three bellwether trials, each of which resulted in jury verdicts in favor of the plaintiffs (including punitive damages verdicts in the last two trials), all the then-pending cases were settled in February 2017 for $671 million. Yet, any *Leach* class member who developed one of the Probable Link diseases after that 2017 settlement is still able to bring suit against DuPont. As present, several dozen new such cases have been filed and are now pending before Judge Sargus in the Southern District of Ohio, with the next trial scheduled to begin later this summer.

At the outset of *In re C-8*, Judge Sargus issued Pretrial Order No. 8 where he ordered that "although the Science Panel findings are available for utilization in [the C8] MDL [in accordance with the *Leach* Settlement], the individual panel members are *not* available for any individual discovery." (Pretrial Order No. 8, *In re C-8*, No. 2:13-MD-2433 (S.D. Ohio Sept. 6, 2013)

(attached as Ex. B) (emphasis added). Despite this order and DuPont's knowledge that the C8 Science Panel was "off limits to any party," DuPont, nevertheless, directly contacted a member of the C8 Science Panel, asked him to sign an inaccurate and self-serving affidavit DuPont's counsel had drafted, and then attempted to introduce that document as evidence in a pending *Leach* class member PFOA injury case. *See Swartz v. E. I. du Pont de Nemours & Co.*, 2020 U.S. Dist. LEXIS 26371, at *106 (S.D. Ohio Feb. 14, 2020) (DuPont put a "hotly contested, unoffered" affidavit of a C8 Science Panel member before a witness "in direct contradiction of sworn statements of lead counsel to this Court."). Not happy with the C8 Science Panels' Findings, DuPont also repeatedly and improperly attacked the Panel's findings throughout the course of the *C-8* litigation, despite its express, written agreement to abide by the C8 Science Panel's Findings.[2]

Unfortunately, this was not an isolated instance of malfeasance by DuPont in the *C-8* MDL (and other litigation[3]), as DuPont was repeatedly admonished by Judge Sargus for improper

[2] *See, e.g., In re C-8*, 2020 U.S. Dist. LEXIS 21793, at *17 (S.D. Ohio Feb. 7, 2020); *In re C-8*, 337 F. Supp. 3d 728, 735-36 (S.D. Ohio July 20, 2015); *In re C-8*, 2019 U.S. Dist. LEXIS 217757, at *95-99 (S.D. Ohio Dec. 18, 2019); *In re C-8*, 348 F. Supp. 3d 650, 678-79 (S.D. Ohio Oct. 24, 2016); *In re C-8*, 2020 U.S. Dist. LEXIS 8950, at *131 (S.D. Ohio Jan. 19, 2020); *In re C-8*, 2016 U.S. Dist. LEXIS 19880, at *1223-45 (S.D. Ohio Feb. 17, 2016).

[3] DuPont's repeated corporate pattern and practice of willful misconduct in litigation, including hiring outside lawyers to appear in federal courts and assert legal arguments that are baseless asserting facts that DuPont *knows* are not true, is well-documented. *See, e.g., Bush Ranch v. E. I. du Pont de Nemours & Co.*, 918 F. Supp. 1524, 1530 (M.D. Ga. 1995) (imposing criminal sanction finding "DuPont's conduct to be the ***most serious abuse*** [this Court has seen] in its years on the bench and the most serious abuse reflected in the legal precedents.") (emphasis added), *rev'd & remanded* 99 F.3d 363, 369 (11th Cir. 1996) (reversing trial court's imposition of criminal sanctions, because "even though DuPont and its counsel may very well have engaged in ***criminal acts***, we must reverse the contempt order because the district court did not afford DuPont the procedural protections the Constitution requires for the imposition of criminal contempt sanctions.") (emphasis added); *Strong v. E. I. du Pont de Nemours & Co.*, 968 So.2d 410, 414 (Miss. 2007) (trial court acted within its discretion by sanctioning DuPont for its ***"abuse of the discovery process"***) (emphasis added); *Kawamata Farms v. United Agri. Prods.*, 948 P.2d 1055, 1098 (Hawaii 1997) (affirming trial court's $1.5 million sanction against DuPont for ***"unprecedented discovery fraud"***) (emphasis added); *Monsanto Co. v. E. I. du Pont de Nemours & Co.*, 2011 U.S. Dist. LEXIS 158214 (E.D. Mo. Dec. 21, 2011) (Court found that DuPont "***perpetrated a fraud against the Court***," "knowingly and in bad faith ***made false representations*** to the Court that are clearly refuted by internal documents produced by" DuPont, showed ***"no remorse for their wrongdoing"*** but to compound the seriousness of their behavior, insist on maintaining their bogus arguments, despite the overwhelming

conduct during the C-8 litigation. *See, e.g.*, *In re C-8*, 204 F. Supp. 3d 962, 966-67, 974, 1119 (S.D. Ohio 2016) (finding that DuPont's legal arguments are "not based on any fact," "untenable," "untrue and disingenuous," and "frivolous and patently false"); *In re C*-8, Evid. Mots. Order No. 26 (S.D. Ohio Aug. 6, 2019) ("The Court cautions DuPont that it will consider granting Plaintiffs' request for fees and costs if DuPont continues to file motions based on nothing more than the desire to make arguments it had the full and fair opportunity to make previously.") (attached at Ex. C).

DuPont's background regarding discovery abuses in general and its conduct in the *C-8* litigation, specifically its refusal to accept the independent Findings of the Science Panel and its attempt to improperly contact Science Panel members in hopes of securing or creating evidence to contradict or undermine the very scientific Findings Dupont contractually agreed never to dispute, in direct violation of court orders, is vital to understand in the context of this motion. That is because DuPont, who in addition to being governed by the *Leach* court's orders and a defendant in pending cases in the *C-8* MDL, is among the collective of defendants that is now trying to send this completely improper subpoena to secure a backdoor way to try to undermine or attack the C8 Science Panel's independent work and Findings. DuPont has had direct, actual notice of the *Leach* orders and the potential contemptuous act of seeking this discovery for many years. And even without the direct participation of DuPont, Defendants' Co-Lead Counsel certainly must be aware, or should be aware, of the history of the *C-8* litigation and the *Leach* and C8 MDL courts' orders, which are all in the public record and make it a contempt of court to issue a subpoena like the one

---

evidence that those arguments are directly contradicted by the facts," thereby making "a mockery of this proceeding," "compromise[ing] the integrity of the case and ***abused the judicial process***" amounting "to ***vexatious conduct***," with "***behavior … so egregious*** that only the most severe sanctions will deter future misconduct.") (emphasis added).

Defendants seek to send to WVU requesting the C8 Health Project an C8 Science Panel data at issue.

Even if Defendants had somehow been able to magically shield themselves from all knowledge of these existing court orders and well-publicized history or had actually forgotten such facts, any legitimate confusion was eliminated when Plaintiffs' Executive Committee ("PEC") sent Defendants an email on April 20, 2020, reciting this history, attaching extra copies of the relevant orders, and asking Defendants to immediately withdraw their improper subpoena to WVU by no later than close of business on April 22, 2020. (*See* attached email at Ex. D.) Defendants refused the PEC's request to comply with the existing court orders and withdraw their subpoena by that date.

On April 24, 2020, counsel for WVU also sent an email to defense counsel asking that the subpoena be withdrawn, citing the existence of the controlling *Leach* court order. (*See* attached email at Ex. K.) To the knowledge of the PEC, Defendants likewise rejected WVU's request to withdraw the subpoena, forcing the PEC to file the instant motion for relief.

PRIOR ORDERS GOVERNING THE C8 HEALTH PROJECT AND C8 SCIENCE PANEL DATA

There are currently four separate protective orders restricting access to the information Defendants are improperly trying to acquire. The first order was entered on May 16, 2008 and provides for the sealing of two groups of data collected through the C8 Health Project between approximately 2006 and 2008. (Order Filing C8 Health Project Data & Establishing Criteria for Future Use of Data, *Leach v. E. I. du Pont de Nemours & Co.*, No. 01-C-608 (Circuit Ct. of Wood Cty, W. Va. May16, 2008) (attached as Ex. E) ("First Order"). The first group of data consisted of a DVD containing individual *Leach* class member participant demographic data, health histories, blood chemistries, and PFAS-related blood levels from the 69,000 class

members who participated in the Health Project, as well as quality assurance data "to assure the accuracy of the testing procedures and results within appropriate scientific parameters." (*Id.* at 1.) The second group consisted of one DVD "that contains all of the data from the first group plus all of the identifying data about Health Project Participants", one DVD "containing all of the data from the first group plus the identifying data [of the] participants who gave their consent to provide [their] identifying information," one DVD containing all the consent forms, and twenty-six DVDs containing scanned documents used to verify identity and eligibility" of the participants. (*Id.* at 1-2.)

At the express request of the *Leach* class members, through class counsel, the *Leach* court ordered that all the disks making up the "first group" and the "second group" were to be sealed as follows:

> The Health Project data contained in the "first group" and the "second group" filed pursuant to this Order shall be sealed, and ***shall not be revealed, copied, or otherwise made available in any form to any person, court, or entity, with or without a subpoena,*** except upon further order of this Court as further prescribed and outlined herein.

(*Id.* at 3 (emphasis added).)

The First Order did provide a potential mechanism for access to the non-identifying C8 Health Project data (meaning the raw data that did not contain information identifying the participants) but *only* upon petition to the *Leach* Court who would appoint one or more "independent scientific evaluator(s)" to advise the court "regarding scientific and other technical or ethical issues related to the" request." (*Id.* at 4). Only after conducting a hearing, would the court consider any order that would allow non-identifiable C8 Health Project data to be released, and, even then, only if the *Leach* Court is convinced that such release "will benefit science, medicine, human health, the class, or society in general." (*Id.* at 4, 5.)

Regarding the "second group" of data, the court ordered as follows:

> WHEREFORE, the Court hereby ORDERS that the information contained in the "second group" of disks shall be sealed and *shall not be disclosed in any manner or form* except in a circumstance where the disclosure is unquestionably necessary for purposes of a matter critical and essential to the life of the C8 Health Project participant for whom disclosure is requested. Therefore, it is the order of this Court that no disclosure of the private records shall be made, and *no request for disclosure or subpoena of those records shall be made by any person or attorney for any person* except in the circumstance where the requestor contends that disclosure is solely in the best interest of the C8 Health Project participant whose records are requested.

(*Id.* at 10 (emphasis added).)

The *Leach* Court also stated:

> It shall be a violation of this Order and a *contempt of this Court* for any attorney to request or acquire an order of any other court or a subpoena in an effort to circumvent the hearing requirements of this Order regarding disclosure of the C8 Health Project data filed in this civil action pursuant to this Order.

(*Id.* (emphasis added).)

The First Order also contemplated the creation of a mechanism to eventually release the non-identifiable C8 Health Project data to a third party who had the "needed infrastructure and expertise for data sharing" to house and potentially distribute the data to appropriate parties and "to evaluate and report to the Court regarding [future] requests for data" so that the *Leach* court would not be burdened with future requests related to the C8 Health Project Data. (*Id.* at 6.)

On January 25, 2013, the *Leach* court entered its second order governing the procedure for any person trying to gain access to the raw data, analyses, or other information collected or generated through the C8 Health Project and C8 Science Panel processes. (Order to File C8 Science Panel Data & Establishing Criteria for Future Use of Data, *Leach v. E. I. du Pont de Nemours & Co.*, No. 01-C-608 (Circuit Ct. of Wood Cty, W. Va. Jan. 25, 2013) (attached as Ex. F) ("Second Order"). That Second Order governs the sealing of two sets of raw data and

analyses done by the independent C8 Science Panel (which used the C8 Health Project raw data, along with other available data, as well as new studies), during its work, which began around the time the C8 Health Project was winding down and continued through the end of 2012. The first data governed by this Second Order is the "Excluded Link Data" that consists of "all data about all participants in any of the health studies, projects, or work undertaken or conducted by the [C8 Science] Panel . . . that the Panel used or relied upon in reaching [its Findings.]" (*Id.* at 1.) This data includes "all demographic data, health histories, blood chemistries, medical data, modeled or modeling data, and exposure data . . . ." (*Id.*) The second data set, the "Identified Link Data," consists of the "Excluded Link Data" "plus all of the data that identifies the individual Participants." (*Id.* at 2.) Just as it had done in its 2008 First Order governing access to the C8 Health Project data, the *Leach* court ordered that this C8 Science Panel data also be filed under seal stating:

> the Filed Data filed pursuant to this Order shall be filed ***under seal and kept sealed***, and shall not be revealed, copied, or otherwise made available in any form to any person, court, or entity, with or without a subpoena, except upon further order of this Court as further prescribed and outlined herein.

(*Id.* at 3 (emphasis in original).)

The mechanism for the disclosure of the C8 Science Panel's "Excluded Link data" in the Second Order was also similar to the disclosure mechanisms outlined in the First Order governing the C8 Health Project data. Upon application to the *Leach* court, the data could be released only "to those with a legitimate scientific interest." (*Id.* at 7.) Regarding the "Identified Link Data," that information could *only* be released to an individual participant or to another "person in a circumstance where the disclosure is unquestionably necessary for purposes of a matter critical and essential to the life of the Participant." (*Id.* at 9.) Also, like the First Order, the Second Order stated:

> It shall be a violation of this Order and a *contempt of this Court* for any attorney to request or acquire an order of any other court or a subpoena in an effort to circumvent the hearing requirements of this Order regarding disclosure of the Filed Data filed in this action pursuant to this Order.

(*Id.* at 9-10 (emphasis added).)

Regarding the "third party mechanism" originally referenced in the First Order, the *Leach* court's Second Order required the parties to "submit proposals for the establishment and implementation of such a third party mechanism . . . ." (*Id.* at 10-11.)

In April 2013, the *Leach* court entered its third order governing any attempts to access C8 Health Project or C8 Science Panel data, analyses, or related information. (Order, *Leach v. E. I. du Pont de Nemours & Co.*, No. 01-C-608 (Circuit Ct. of Wood Cty, W. Va. Apr. 22, 2013) (attached as Ex. G) ("Third Order"). The Third Order confirmed that the Robert C. Byrd Health Sciences Center at WVU would serve as the "third party mechanism" referenced in the *Leach* Court's First and Second Orders "to oversee, implement, manage, and administer all aspects of data sharing with regard to all data generated" by the C8 Health Project and/or C8 Science Panel. (*Id.* at 1, ¶ 1). WVU was tasked with receiving electronic copies of "All Filed Data," while the *Leach* court retained the original filings and any non-electronic filings. (*Id.* at 4.) WVU was authorized to "create a process wherein members of the *scientific or academic communities* may utilize the data in "All Filed Data" and/or related serum stored in the WVU Tissue Bank for reasons *that will benefit science, medicine, human health, the Class, or society in general*" and are "consistent with the [First and Second Orders] . . . ." (*Id.* at 5.) The plain language of the Third Order, in addition to recognizing that the First and Second Orders were still in effect, limits the release of "Filed

Data" only to scientific or academic communities and there is no exception for defense attorneys to gain access to the data for litigation purposes.[4] Indeed, the court specifically stated:

> [t]he intent of the court in transferring these data to WVU includes but is not limited to: (a) reporting individual data to the affected and rightful owners of the data (the individual so-identified and with appropriate safeguards, and (b) enabling scientists to use the data under appropriate conditions.

(Id. at 7.) The *Leach* court further stated that

> No institution, including WVU, should release Protected Health Information (PHI) except to rightful owners, such as the individuals themselves or their guardians(s). Further, WVU will not release individually identifiable or individual level data to third parties under *any* conditions, whether PHI or not.

(*Id.* (emphasis added).)

WVU also has "the right, at their discretion and with justification, to deny access to the [Filed] data if the representing parties cannot meet the requirements" of either being a scientist or seeking the data for legitimate and documented scientific purposes. (*Id.* at 6.) Notwithstanding WVU's right to deny access to the data, the First and Second Order were not modified and are still in effect. Therefore, while a scientist may submit a proposal for a legitimate scientific study that includes a request for the non-identifying data directly to WVU, an attorney is still prohibited from unilaterally submitting a subpoena for the information, and to do so is contempt of court.

On September 4, 2013, the *Leach* court entered an amended version of the Third Order. (Amended Order, *Leach v. E. I. du Pont de Nemours & Co.*, No. 01-C-608 (Circuit Ct. of Wood Cty, W. Va. Sept. 24, 2013) (attached as Ex. H) ("Amended Order"). This Amended Order simply modified paragraph number five on page two and paragraph number two on page three of the Third

[4] In fact, at that Hearing before the First Order was entered, DuPont vigorously argued to the Court that it should be allowed access to the data, which the *Leach* court rejected in its subsequent orders. (April 12, 2013, Hr'g Tr., *Leach v. E. I. du Pont de Nemours & Co.*, No. 01-C-608, at 46:14-16 (Circuit Ct. of Wood Cty, W. Va.) (attached as Ex. I). Indeed, the representative from WVU who testified at the hearing stated that if an attorney wanted information they would have to "be part of the scientific and academic community that would propose a project." (*Id* at 44:19-21.)

Order relating to the identity of the receiving parties at WVU. No other modifications were made to the Third Order.

LEGAL ARGUMENT

A party without standing to quash a nonparty subpoena, however, does have standing to seek a protective order over the documents sought by a subpoena under Rule 26 standards. *Kappel v. Garris*, 2020 U.S. Dist. LEXIS 24485, at *7 (D. S.C. Feb. 12, 2020) (citing cases); *see also HDSherer LLC v. Nat. Molecular Testing Corp.*, 292 F.R.D. 305, 307-08 (D. S.C. 2013) ("a party may move for a protective order . . . regardless of whether the moving party is seeking to prevent disclosure of information by a nonparty, as long as the moving party can tie the protected information to an interest listed in the rule") (citation omitted). "The scope and conduct of discovery are within the sound discretion of the district court." *Columbus—Am. Discovery Grp. v. Atl. Mut. Ins. Co.*, 56 F.3d 556, 568 n.16 (4th Cir. 1995) (citations omitted).

Rule 26(c) provides that a court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression or undue burden or expense by, among other things, forbidding disclosure of confidential research. Fed. R. Civ. P. 26(c)(1)(G). *United States v. Saddler*, 789 Fed. Appx. 952, 954 (4th Cir. 2019) (citation omitted). Here, Defendants have clearly improperly requested confidential information in the form of personal identifiable information from the participants of the C8 Health Project and the C8 Science Panel work that the *Leach* court held is not publicly available. For example, Defendants have requested "family medical history, pregnancy history and pregnancy-related outcomes for women, information about lifestyles and health behaviors" in addition to other personal information. (Subpoena at 9.) Defendants cannot genuinely argue that this information is not confidential pursuant to the *Leach* Orders governing this information, as the First and Second Orders specifically state that personal information is only

available to the individual participants or another person where the disclosure is necessary for purposes critical and essential to the life of the Participant. (First Order at 10; Second Order at 5.) Defendants also cannot genuinely argue that the requested information is not potentially embarrassing to many members of the *Leach* class, as some of the requested information, for example pregnancy related outcomes such as a miscarriage, touches on one of the most personal, highly-sensitive and deeply emotional experiences that people encounter in their lives. Furthermore, the information regarding the requested specific identifiable information is not relevant to this case as no *Leach* class member has a claim in this MDL. The information that Defendants request can only be interpreted as an attempt to annoy and embarrass the *Leach* class members and is clearly irrelevant to issues before this Court, in addition to being confidential and sealed pursuant to the *Leach* court orders.

Moreover, it is most telling that none of the Defendants, including DuPont, ever attempted to violate the pending *Leach* Orders at issue protecting this data from discovery in any case where a *Leach* class member was represented or had asserted claims during any of the preceding *eleven years* since the *Leach* court began entering these orders. It is only now, in the context of a legal proceeding where no *Leach* class member is a party and where Defendants, including DuPont, believe they are not required to copy or alert any *Leach* class counsel to their "non-party subpoena" to WVU,[5] that Defendants are attempting to secure the data from WVU without complying with – and in direct violation of - the *Leach* court orders. Fortunately, Advisory Counsel to the PEC, who also happens to be class counsel for the *Leach* class, found out about the WVU subpoena through the PEC and has alerted the PEC to the impropriety of Defendants' actions in this regard.

[5] *See e.g.*, April 24, 2020, Joint Status Report (Defendants claim the PEC has no "standing" to oppose their subpoena to WVU because WVU is a "non-party" in this litigation and none of the PEC represent WVU) (attached as Ex. J).

Defendants should not be allowed to use these legal proceedings as a way to evade or do an end-run around the *Leach* class members' rights established under multiple court orders in separate legal proceedings.

Regarding the non-identifiable data, the *Leach* court expressly stated that this information is *only* available for legitimate academic and scientific purposes – not for legal defense arguments and experts. Moreover, the *Leach* court *specifically* warned attorneys that any attempt to access this information through the order of another court or through a subpoena *is contempt of court*. Because a district court is afforded "substantial discretion in managing discovery," *Lone Star Steakhouse & Saloon v. Alpha of Va., Inc.*, 43 F.3d 922, 929 (4th Cir. 1995), and because "[c]ourts are particularly wary of non-party subpoenas seeking documents that are already the subject of a protective order in other litigation," *Conrey v. IBM Corp.*, 2019 U.S. Dist. LEXIS 193395, at*6 (E.D. Pa. Nov. 6, 2019), this Court should enter a protective order forbidding Defendants from accessing this information or even attempting to do so in any manner not fully consistent with the existing *Leach* court orders.

CONCLUSION

For the reasons set forth above, Plaintiffs respectfully request that this Court issue a protective order pursuant to Rule 26 prohibiting Defendants from pursuing or seeking to enforce their subpoena to WVU or taking any action tin that regard hat is not permitted and consistent with the procedures protecting the C8 Health Project and C8 Science Panel data under the existing *Leach* court orders.

Dated: April 27, 2020

/s/ Fred Thompson, III
Motley Rice LLC
28 Bridgeside Boulevard
Mt. Pleasant, SC 29464
P: (843) 216-9000
Fax: 843-216-9440
fthompson@motleyrice.com

Plaintiffs' Liaison Counsel

-and-

/s/ *Michael A. London*

Michael A London
Douglas and London PC
59 Maiden Lane
6th Floor
New York, NY 10038
P: (212)-566-7500
F: (212)-566-7501
mlondon@douglasandlondon.com

Paul J. Napoli
Napoli Shkolnik PLLC
1301 Avenue Of The Americas
10th Floor
New York, NY 10019
P: (212)-397-1000
F: (646)-843-7603
pnapoli@napolilaw.com

Scott Summy
Baron & Budd, P.C.
3102 Oak Lawn Avenue
Suite 1100
Dallas, TX 75219
P: (214)-521-3605
ssummy@baronbudd.com

Co-lead Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was electronically filed with this Court's CM/ECF on this 27th day April, 2020 and was thus served electronically upon counsel of record.

/s/ Fred Thompson, III

EXHIBIT

C-144

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

IN RE: AQUEOUS FILM-FORMING FOAMS PRODUCTS LIABILITY LITIGATION	MDL No. 2:18-mn-2873-RMG

PLAINTIFFS' REPLY BRIEF IN SUPPORT OF MOTION FOR PROTECTIVE ORDER REGARDING SUBPOENA TO WEST VIRGINIA UNIVERSITY

Plaintiffs, by and through Counsel, respectfully file this Reply in support of their Motion for Protective Order Regarding Defendants' Third Party Subpoena to West Virginia University [ECF No. 564]. Plaintiffs recognize that replies are "discouraged" under Local Rule 7.07 because they tend to repeat arguments included in an opening memorandum and raise new arguments for the first time . . . ." *Bouchard v. Potter*, 2013 U.S. Dist. LEXIS 45237, at *5 n.4 (D.S.C. 2013). Therefore, Plaintiffs' Reply will focus on Defendants' inaccurate represention of facts in Defendants' Opposition [ECF No. 591] ("Opp'n") as well as reply to legal issues raised by Defendants and will not needlessly repeat previous arguments or raise new arguments in compliance with Local Rule 7.07.

Defendants' argument that their purported reasons for seeking the C8 study data are allowed under the existing *Leach* court orders is wrong. Defendants' Opposition make clear that they are *not* seeking the data to perform any new scientific study or additional work contemplated by the *Leach* court orders/procedures. Instead, Defendants confirm they seek only to reanalyze and criticize the *existing* work and *existing* results/analyses – not to add any new data/scientific studies. Defendants state that "only by getting the de-identified data can Defendants and their experts determine whether the [existing] studies were reliably conducted

and appropriately considered all relevant factors and potential confounding variables." (Opp'n at 9-10.)

Defendants' plan is not to do anything new that benefits society as a whole, as required under the relevant *Leach* Orders, but to simply "allow Defendants and their own consultants and experts to subject the [existing] research and findings to a critical analysis . . . ." (*Id.* at 2.) Defendants expressly acknowledge that they do not want to abide by any existing court orders that would render them "powerless to undermine or attack or malign the work overseen by the C8 Science Panel." (*Id.* at 11.) Defendants note that their desire is not to do any new research, advance the science or study the data but only to "undermine" the existing data and studies. (*Id.* at 11.) This purpose, however, is expressly prohibited under the existing court orders authorizing the release of the data only for reasons "that will benefit science, medicine, human health, the Class or society in general." (Pls' Mot. at 13) (citing orders).

Defendants also incorrectly argue in a footnote that West Virginia University ("WVU") does not have the discretion to deny access to the data. (Opp'n at 6, n.2.) Defendants completely ignore specific statements made by WVU and DuPont's own attorney recognizing that it is up to WVU and its designated scientific advisors to assess and evaluate any proposed use/access to this data and only those entities are empowered to determine what is an appropriate purpose for accessing this data – not Defendants and, respectfully, not another court.

Indeed, at the hearing where a draft of the Third Order was discussed, the WVU representative made clear how the process of obtaining the publicly available information would occur:

> A. So what we would do is we would create a mechanism whereby interested scientists or researchers would be able to understand the content of the data set and develop a research question and protocol. They would be required to seek -- have IRB approval from their institution as well as from ours. And then they would work

> with us and we would actually it's called running the code. So they would develop a statistical analytical code. We would help them develop that code. We would actually run it for them on the data sets and then give them back their results.
>
> Q. So in other words, the other institution, after they get their institutional review board approval, would submit essentially a set of -- for the lack of a better way to describe it -- questions about the data?
>
> A. Correct.
>
> Q. And the people at West Virginia University would run those question[s] through the data set and then send back the responses?
>
> A. Correct.
>
> Q. So that the requesting institution wouldn't actually have the data and wouldn't have any ability to mine --
>
> A. Correct
>
> Q.-- individual data from the data?
>
> A. Absolutely.

(Apr. 12, 2013, Hr'g Tr., *Leach v. E. I. du Pont de Nemours & Co.*, No. 01-C-608, at 20:1-24 (Circuit Ct. of Wood Cty, W. Va.) (attached as Ex. I [ECF No. 564-9] to Pls' Mot.).)

> A. What we are contemplating is making the data dictionary and the content of the data fields may be a better term -- publicly available. Researchers would then make proposals, send us their code or algorithms -- statistical algorithms. We would run -- we would run those for them on the data set and then send them back their results. So the actual physical data set would never leave secured WVU computers.

(*Id.* at 40:13-20.)

Even DuPont's own attorney recognized that WVU had the discretion as to what information could be made public:

> MR. LEES: There's nothing in there that sets any parameters as what can or cannot be made public. That's how I'm reading the order. And she is saying -- and I understand what she's saying is the IRB sets the parameters.

(*Id.* at 41:21-24.)

> Q. My point is I don't see any of that in this order anywhere. So essentially if the order is signed as proposed, the Court is leaving it up to the discretion of the IRB as to how to make this public or not, fair enough?
>
> A. Correct, yes.

(*Id.* at 43:3-6.)

Moreover, DuPont's attorney recognized at the time that he did not "believe it was the Court's original intent for this to be a discovery mechanism or a study designed to assist [parties] in their litigation," (*id.* at 53:8-10), and that the data "*wasn't to be used for some mechanism to make it easier to sue one party or not*." (*Id.* at 54:10-11.) (emphasis added)

Furthermore, and most importantly, even if Defendants submitted an appropriate request to access the data for some new scientific study, they would never be entitled to actually receive any of the underlying data. The April 12, 2013 hearing transcript cited above above makes clear how the process would work: defendants would have to submit a proposal, get Independent Review Board ("IRB") approval for the proposed new study, and then if WVU and its review board approves, WVU would then run the analysis of the data for the requestor and then give them the results – the requestor would never actually get the raw data. WVU would do whatever analysis of the data was approved and requested and would then report the results back to the requestors.

Given the Defendants' demonstrated understanding of the restrictions on the use of the C8 study data at the time, Defendants new-found self-proclamation that they have a valid objective is meaningless and irrelevant. Defendants' Opposition completely ignores the fact that Plaintiffs submitted an email from WVU's counsel expressly asking Defendants to withdraw the subpoena based on the existing *Leach* Court orders. (Email from Harry P. Montoro, Senior Assoc. Gen. Counsel, WVU, to Liam Montgomery, Defs' co-lead counsel (Apr. 24, 2020))

(attached as Ex.I [ECF No. 564-11] to Pls. Mot.) Defendants not only fail to address WVU's position on this matter,[1] but they also fail to explain why Defendants did not respond to WVU at all.

Regarding the issue of confidential/sealed personal medical data, Defendants argue that WVU has been told it may choose to "de-identify" the data, (Opp'n at 5), but that doesn't change the fact that the subpoena is requesting its production – and nothing in the subpoena tells WVU that it must do anything other than simply turn it over as is, if ordered by this Court to "comply" with this subpoena. Moreover, Defendants essentially concede that the confidential data is within the scope of their subpoena by arguing that it can be marked "confidential" under this Court's MDL protective order. (*Id.* at 10-11.) But that doesn't change the fact that the confidential data is being demanded to be produced under this subpoena. There would be no need to reference the protective order or have anything marked "confidential" under the MDL protective order if the subpoena was somehow carving out such confidential data from its scope, and that is because it does not.

Defendants' argument that the DuPont entities are not involved in this subpoena "in any way" is non-sensical. (*Id.* at 7.) There is no representation being made by Defendants that, if data is turned over by WVU, that data would not then be made available to all Defendants in this MDL and that DuPont would not have equal access to all the data with no limits on its use.

Finally, when considering whether to recognize a state court's protective order, a federal court typically considers the nature of the protective order. Where a state court protective order

[1] Defendants' argument that the *Leach* Class also is not objecting and should be ignored here is wrong. Although the individual class members are not parties in this MDL, one of the *Leach* Class Counsel is Advisory Counsel to the Plaintiffs' Executive Committee in this case and is advising the PEC on the facts and history of these issues so that the rights of those class members are not violated by Defendants who are seeking to improperly access their personal data in a case where they received no notice and Defendants claim they have no right to object. In light of Defendants' argument that the *Leach* class members and their class counsel have no standing to object here, *Leach* class counsel is separately filing their own motion to quash in West Virginia federal court.

is more of an "agreement between counsel" or ministerial act a federal court is less inclined to enforce the state court order. *Tucker v. Ohtsu Tire & Rubber Co.*, 191 F.R.D. 495, 501 (D. Md. 2000). However, in situations where a state court protective order is issued after a deliberative process that includes a full hearing and briefing, which is the case here, a federal court is more inclined to enforce the state court order. *Id*; *see also Donovan v. Lewnowski*, 221 F.R.D. 587, 589-90 (S.D. Fla. 2004) (recognizing that there is a need for more deference when a state court protective order is entered "after a full consideration of the merits of a fully briefed dispute."); *Lower Town Project, LLC v. Lawyers Title Ins. Corp.*, 2012 U.S. Dist. LEXIS 27270, at *12 (E.D. Mich. Feb. 29, 2012) (recognizing that although a federal court is not bound to follow a state court protective order, a federal court will not "permit[] a party to flout a state court protective order simply because documents in a state action might prove useful in a separate federal action") (citation omitted).

For these reasons, as well as those expressed in our moving papers, the Motion for Protective Order should be granted.

Dated: May 19, 2020

/s/ Fred Thompson, III
Motley Rice LLC
28 Bridgeside Boulevard
Mt. Pleasant, SC 29464
P: (843) 216-9000
Fax: 843-216-9440
fthompson@motleyrice.com

Plaintiffs' Liaison Counsel

-and-

/s/ *Michael A. London*

Michael A London
Douglas and London PC
59 Maiden Lane

6th Floor
New York, NY 10038
P: (212)-566-7500
F: (212)-566-7501
mlondon@douglasandlondon.com

Paul J. Napoli
Napoli Shkolnik PLLC
1301 Avenue Of The Americas
10th Floor
New York, NY 10019
P: (212)-397-1000
F: (646)-843-7603
pnapoli@napolilaw.com

Scott Summy
Baron & Budd, P.C.
3102 Oak Lawn Avenue
Suite 1100
Dallas, TX 75219
P: (214)-521-3605
ssummy@baronbudd.com

Co-lead Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was electronically filed with this Court's CM/ECF on this 19th day of May, 2020 and was thus served electronically upon counsel of record.

/s/ Fred Thompson, III

EXHIBIT

C-145

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

IN RE: AQUEOUS FILM-FORMING FOAMS PRODUCTS LIABILITY LITIGATION	MDL No. 2:18-mn-2873-RMG **ORDER** **This Order Relates to All Actions.**

The Court conducted a status conference on June 5, 2020, during which it heard oral arguments on four motions pending before the Court.

I. Plaintiffs' Motion for a Protective Order Regarding Defendants' Third-Party Subpoena to West Virginia University (Dkt. No. 564)

Plaintiffs move for a protective order pursuant to Rule 45 or Rule 26 of the Federal Rules of Civil Procedure directed to the April 6, 2020 subpoena served by Defendants' Co-Lead Counsel on third-party West Virginia University Robert C. Byrd Health Sciences Center ("WVU"). Defendants' Co-Lead Counsel now represent to the Court and to Plaintiffs' Co-Lead Counsel that they withdraw the subpoena. Plaintiffs' Co-Lead Counsel similarly represent that they withdraw a motion to quash the subpoena pending before District Court for the Northern District of West Virginia, Misc. Action No. 1:20-mc-00025-TSK. The Court **DIRECTS** that any further effort to obtain by subpoena the documents at issue and under seal by the West Virginia Circuit Court of Wood County shall be initiated only after first unsuccessfully seeking access to the documents from WVU and the West Virginia Circuit Court of Wood County, by a motion to this Court requesting to subpoena the documents notwithstanding the West Virginia Circuit Court's order.

Plaintiffs' motion for a protective order (Dkt. No. 564) is **DENIED AS MOOT.**

II. Plaintiffs' Motion to Compel Discovery from E.I. DuPont de Nemours and Company; The Chemours Company; The Chemours Company FC, LLC; Corteva, Inc.; and DuPont de Nemours, Inc. (Dkt. No. 581)

Plaintiffs move to compel E.I. DuPont de Nemours and Company; The Chemours Company; The Chemours Company FC, LLC; Corteva, Inc.; and DuPont de Nemours, Inc. (the "DuPont-Related Entities") to produce certain documents including Conveyance Agreements and Ancillary Agreements requested in Plaintiffs' AFFF Liability Notice.

Parties to a civil litigation may obtain discovery regarding "any nonprivileged matter that is relevant to any party's claim or defense" including information that "appears reasonably calculated to lead to the discovery of admissible evidence." Fed. R. Civ. P. 26(b)(1). Courts broadly construe rules enabling discovery, but certain limits may be imposed. *Nat'l Union Fire Ins. Co. of Pittsburgh, Pa. v. Murray Sheet Metal Co.*, 967 F.2d 980, 983 (4th Cir. 1992); *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 (1978). The court "must limit the frequency or extent of discovery . . . if it determines that the discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive." Fed. R. Civ. P. 26(b)(2)(C)(i). Nevertheless, "scope and conduct of discovery are within the sound discretion of the district court." *Columbus–Am. Discovery Grp. v. Atl. Mut. Ins. Co.*, 56 F.3d 556, 568 n.16 (4th Cir. 1995); *see also Carefirst of Md., Inc. v. Carefirst Pregnancy Ctrs.*, 334 F.3d 390, 402 (4th Cir. 2003) ("Courts have broad discretion in [their] resolution of discovery problems arising in cases before [them]." (alternations in original and internal quotation marks omitted)). If a party declines to answer a request for production, the serving party "may move for an order compelling an answer, designation, production, or inspection." Fed. R. Civ. P. 37(a)(3)(B). The district court will treat an "evasive or incomplete" discovery response as "a failure to disclose, answer, or respond." Fed. R. Civ. P. 37(a)(4). A

document is under a party's possession, custody or control if the party has the "practical ability" or "legal right" to obtain the documents. *Wade v. Chase Bank USA, N.A.*, No. 2:12-cv-3565, 2013 WL 12154986, at *2 (D.S.C., Nov. 7 2013) (surveying cases).

Having heard the Plaintiffs' and each DuPont-Related Entity's arguments and in consideration of the significant discovery necessary to effectively address the merits of the claims in this multi-district litigation, the Court **GRANTS** Plaintiffs' motion to compel. (Dkt. No. 581.) Each DuPont-Related Entity is **DIRECTED** to produce all Conveyance Agreements and all Ancillary Agreements not yet produced. These parties are further **DIRECTED** to continue to meet-and-confer regarding any outstanding deposition scheduling raised in Plaintiffs' motion.

III. Motion to Seal by Defendants E.I. Du Pont de Nemours and Company; Corteva, Inc.; and Du Pont de Nemours, Inc. (Dkt. No. 598) and Motion to Seal by Plaintiffs (Dkt. No. 605)

Defendants E.I. Du Pont de Nemours and Company; Corteva, Inc.; and Du Pont de Nemours, Inc. move the Court to seal approximately 1,000 pages of exhibits to their response in opposition to Plaintiffs' motion to compel discovery. Plaintiffs in turn seek to seal approximately 100 pages of exhibits to their reply in support of their motion to compel. The Court conducted an *in camera* review of the exhibits. These Defendants and the Plaintiffs now represent that they withdraw their respective motions to seal.

The motions (Dkt. No. 598, No. 605) are therefore **DENIED AS MOOT**.

AND IT IS SO ORDERED.

s/ Richard Mark Gergel
Richard Mark Gergel
United States District Judge

June 5, 2020
Charleston, South Carolina

EXHIBIT

C-146

UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

IN RE: AQUEOUS FILM-FORMING FOAMS PRODUCTS LIABILITY LITIGATION MDL No. 2873

ORDER DENYING TRANSFER

Before the Panel: Several defendants[1] in the Southern District of Ohio *Hardwick* action listed on Schedule A move under 28 U.S.C. § 1407(c) to transfer *Hardwick* to the District of South Carolina for inclusion in MDL No. 2873. Plaintiff opposes the motion.

MDL No. 2873 involves allegations that aqueous film-forming foams (AFFFs) used at airports, military bases, or other locations to extinguish liquid fuel fires caused the release of perfluorooctane sulfonate (PFOS) and/or perfluorooctanoic acid (PFOA) into local groundwater and contaminated drinking water supplies. Before the Panel centralized this docket, *Hardwick* was noticed as a potentially related action. Plaintiff in *Hardwick* asserts claims against various manufacturers of per- or polyfluoroalkyl substances (PFAS, an umbrella term that includes PFOS and PFOA) on behalf of a putative nationwide class of all individuals with a detectable level of PFAS in their blood. Plaintiff primarily seeks as relief the creation of an independent panel of scientists to study and evaluate health effects or illnesses, if any, caused by PFAS exposure. The *Hardwick* complaint contains few mentions of AFFFs.

When we centralized this docket, we denied a motion by 3M to extend the scope of the MDL to encompass not just cases involving AFFFs, but all cases relating to 3M's manufacture, management, disposal, and sale of PFAS. *See In re Aqueous Film-Forming Foams Prods. Liab. Litig. (In re AFFF)*, 357 F. Supp. 3d 1391, 1396 (J.P.M.L. 2018). Plaintiff in *Hardwick* sought inclusion in the proposed "PFAS MDL," while defendants opposed including *Hardwick* in the MDL.[2] At oral argument on the centralization motions, counsel for defendant Daikin America, Inc., described *Hardwick* thusly:

> *Hardwick* doesn't involve groundwater, it doesn't involve AFFF; *Hardwick* is simply a question about the curiosity of an individual plaintiff who says, There is some part of this chemical in my blood, and I'd like to know if I may be at risk. And I'd want a class action, a nonopt-out (b)(2) class action on behalf of all Americans to

[1] Moving defendants include: Arkema, Inc.; Arkema France, S.A.; Daikin Industries, Ltd.; Daikin America, Inc.; E.I. du Pont de Nemours and Company; The Chemours Company, LLC; Solvay Specialty Polymers USA, LLC; and 3M Company.

[2] The parties have now reversed positions with respect to including *Hardwick* in the MDL.

> determine not whether I am injured or whether they are injured, but, rather, how the determination of general causation should be made. He wants to have a scientific panel appointed to determine which diseases are caused by exposure to these chemicals, and then to have that binding in any litigation thereafter.

Oral Arg. Tr. at 53:22–54:7, *In re AFFF*, MDL No. 2873 (J.P.M.L. Nov. 29, 2018), ECF No. 244. After the Panel centralized MDL No. 2873, the Panel Clerk determined that *Hardwick* was not appropriate for inclusion in the MDL. *See* Notice to Counsel, *In re AFFF*, MDL No. 2873 (J.P.M.L. Dec. 10, 2018), ECF No. 241.

In support of their motion to transfer, defendants now offer a different characterization of *Hardwick*—as an individual action for medical monitoring by a single firefighter allegedly exposed to PFAS contained in AFFF products. Defendants point to two paragraphs of the complaint that actually reference AFFFs: one describes plaintiff's background as a firefighter and his potential exposure to AFFFs; the other discusses the various means by which defendants promoted PFAS use. *See* Am. Compl. ¶¶ 4 & 61, *Hardwick v. 3M Co.*, C.A. No. 2:18-01185 (S.D. Ohio Apr. 16, 2019), ECF No. 96. Defendants also contend that the *Hardwick* court's recent decision denying their motions to dismiss makes clear that plaintiff seeks only "traditional medical monitoring," thus rendering his case no different than other medical monitoring cases in the MDL. Defendants argue that discovery concerning AFFF contamination sites and issues will be necessary in *Hardwick* and, therefore, that transfer to MDL No. 2873 is appropriate.

We do not find this new characterization of *Hardwick* persuasive. The focus of *Hardwick* is entirely on PFAS, with only two tangential references to AFFFs. There are no claims directed to AFFF products or AFFF manufacturers (at least, not with respect to their manufacture of AFFF products). Moreover, the claims in *Hardwick* explicitly apply to all forms of PFAS,[3] whereas only two of these (PFOA and PFOS) are alleged to have been used in AFFF products. Plaintiff also seeks relief—in the form of a "PFAS science panel"—that is not sought by plaintiffs in the MDL. In short,

---

[3] The forms of PFAS identified in the *Hardwick* complaint include:

> perfluorooctanoic acid ("PFOA") and perfluorooctane sulfonic acid ("PFOS") and related chemicals, including but not limited to those that degrade to PFOA and/or PFOS, and including but not limited to C3-C-15 PFAS chemicals, such as perfluorohexanesulfonate (PFHxS), perfluorononanoate (PFNA), perfluorobutanesulfonate (PFBS), perfluorohexanoate (PFHxA), perfluoroheptanoate (PFHpA), perfluoroundecanoate (PFUnA), perfluorododecanoate (PFDoA), HFPA Dimer Acid (CAS #13252-13-6/C3 Dimer Acid/P-08-508/FRD903/GX903/C3DA/GenX), and HFPA Dimer Acid Ammonium Salt (CAS# 62037-80-3/ammonium salt of C3 Dimer Acid/P-08-509/FRD902/GX902/GenX) . . . .

Hardwick Am. Compl. ¶ 1.

Hardwick is not an AFFF action of the type encompassed by MDL No. 2873.

None of the proceedings in *Hardwick* to date undermine this conclusion. Although defendants characterize *Hardwick* as an "individual action," the *Hardwick* court has not yet considered whether plaintiff's proposed class can be certified. *See Hardwick v. 3M Co.*, C.A. No. 2:18-01185, 2019 WL 4757134, at *2 (S.D. Ohio Sept. 30, 2019) ("[T]he Court reviews only the plausibility of Mr. Hardwick's individual claims and makes no determination as to whether they are appropriate for class certification."). Nor did the court hold that plaintiff's claims are limited to "traditional" forms of medical monitoring, but rather that medical monitoring encompasses the unique relief that plaintiff seeks. *See id.* at *11 ("The Court notes, however, that requesting oversight of further scientific study in some fashion in an Ohio tort claim with medical monitoring as the remedy is not exceptional. Indeed, it is not new to this Court.").

Furthermore, our past practice in this docket weighs *against* transferring *Hardwick* to MDL No. 2873. We have transferred several actions in which plaintiffs allege multiple sources of PFOS and PFOA contamination, including from the use of AFFFs. *See, e.g.*, Transfer Order at 2, *In re AFFF*, MDL No. 2873 (J.P.M.L. July 31, 2019), ECF No. 483. We have not, though, transferred to the MDL actions that do not contain *any* allegations or claims relating to AFFF use. Indeed, we recently denied transfer of an action, *Middlesex*, in which the claims were "directed at 3M and its manufacture, marketing, and sales of PFOS and PFOA, not its manufacture of AFFF products." *See* Order Denying Transfer at 1, *In re AFFF*, MDL No. 2873 (J.P.M.L. Dec. 18, 2019), ECF No. 541. In that order, we expressed our concern that broadening the scope of MDL No. 2873 beyond AFFFs could render the litigation unwieldy:

> [W]e have no desire to unnecessarily complicate the transferee judge's task in efficiently managing this litigation, which already involves a wide range of claims and parties. Given our continued concern about the manageability of this litigation, *a party seeking transfer of an action that does not on its face raise AFFF claims bears a significant burden to persuade us that transfer is appropriate and will not undermine the efficient progress of the AFFF MDL.*

Id. at 2 (emphasis added).

Like *Middlesex*, the *Hardwick* complaint does not on its face raise AFFF claims, and defendants have not carried their "significant burden" to persuade us that transfer of this non-AFFF action is appropriate. To the contrary, transferring *Hardwick* would introduce the additional "site-specific issues, different modes of PFAS contamination, and different PFAS chemicals" that concerned the Panel when we declined to include non-AFFF actions in the MDL. *See In re AFFF*, 357 F. Supp. 3d at 1396.

Defendants' prediction that discovery in *Hardwick* will substantially overlap with discovery conducted in the MDL is speculative. The *Hardwick* court only recently denied defendants' motions to dismiss the complaint, and no discovery has taken place. When defendant Daikin America, Inc.,

opposed including *Hardwick* in the MDL during briefing on the initial motions to centralize this litigation, counsel suggested that any discovery relating to AFFFs would be minimal. *See* Daikin Opp. at 4, MDL No. 2873 (J.P.M.L. Nov. 21, 2019), ECF No. 228 ("[I]f the case were to proceed beyond initial motion practice, novel questions of class certification for a non-opt-out class of virtually all Americans would be the center of remaining litigation. These questions have absolutely nothing to do with the pretrial questions and practice of the AFFF cases."). Defendants' current suggestions otherwise are not convincing. To the extent there is any potential for duplicative discovery, such overlaps—given the stark differences between *Hardwick* and the actions in the MDL—are best minimized through coordination between the parties and the involved courts. And, should *Hardwick* evolve into an AFFF case, the parties or the court at that time can re-notice *Hardwick* as a potential tag-along in MDL No. 2873.

IT IS THEREFORE ORDERED that the motion to transfer the action listed on Schedule A to MDL No. 2873 is denied.

PANEL ON MULTIDISTRICT LITIGATION

Karen K. Caldwell
Chair

Ellen Segal Huvelle	R. David Proctor
Catherine D. Perry	Nathaniel M. Gorton
Matthew F. Kennelly	David C. Norton

IN RE: AQUEOUS FILM-FORMING FOAMS PRODUCTS LIABILITY LITIGATION MDL No. 2873

SCHEDULE A

Southern District of Ohio

HARDWICK v. 3M COMPANY, ET AL., C.A. No. 2:18−01185

EXHIBIT

C-147

May 22, 2020

VIA EMAIL

Judge Edmund A. Sargus, Jr.
Chief Magistrate Judge Elizabeth A. Preston Deavers
Joseph P. Kinneary U.S. Courthouse, Rooms 225 & 301
85 Marconi Boulevard
Columbus, OH 43215

Re: *Hardwick v. 3M Co., et al.*, No. 2:18-cv-1185

Dear Judge Sargus and Chief Magistrate Judge Deavers:

We write as counsel to Daikin America, Inc. and (subject to the pending motion for reconsideration) Daikin Industries, Ltd., and on behalf of all Defendants, in compliance with the Court's preliminary pretrial order (ECF No. 156 (Apr. 30, 2020)), to outline Defendants' position on the timing of Plaintiff's Motion for Class Certification.

The Parties' Positions in the Rule 26(f) Report. In the parties' Rule 26(f) Report—which was filed on February 19, 2020, before the COVID-19 crisis hit—the parties agreed that any motion for class certification would be filed by December 31, 2020. *See* ECF No. 147 at 2. But the parties disagreed about whether Plaintiff could file his motion, as Plaintiff desired, long before that date. Defendants opposed that request both because Defendants were concerned they could be squeezed by discovery requests on a short time frame and because Defendants would need to take significant class-related discovery of their own and consult with and rely upon experts in a number of fields for their opposition. At the time the Rule 26(f) Report was filed, no discovery had been noticed or requested by either side (and none has been commenced since). Defendants consequently proposed a window of September 30 through December 31, 2020 for the filing of the motion, allowing for an orderly process of class-related discovery generally.

Changes Since the Rule 26(f) Report. The world has changed since the parties filed that report. COVID-19 shut down this Court and halted all activity in this case. Discovery never commenced. For some period of time going forward, even with phased re-openings in some areas of the country, progress will be slowed. Several of the parties and some of the third parties from whom discovery will be sought are operating at remote locations; some, such as healthcare providers, have suspended normal practices; and some remain subject to orders in various states impeding access to buildings, files, and individuals.

Defendants' Position. The parties' agreement that any motion for class certification would be filed by December 31, and Defendants' contention that the earliest date for filing should be September 30, were premised on a world not interrupted by a global pandemic. Because of the delays already engendered and the continuing uncertainty as a result of COVID-19, the parties agreed at a meet-and-confer on May 18 that Plaintiff be given a deadline to file his class-certification motion of April 30, 2021.

Plaintiff nonetheless suggested that he will move for class certification in the near future, asserting that he has discovery from another case or other cases (involving a subset of these Defendants) and therefore will not require significant class-certification-related discovery in this case. (The issue whether such discovery can be deemed produced in this case, particularly when it has not been shared with the other Defendants, is reserved.) Defendants, however, will require

substantial class-certification-related discovery and expert work to respond to that motion—all of which has been and will continue to be affected by the COVID-19 crisis. Accordingly, Defendants request as follows based on the representation that Plaintiff will not take substantial discovery prior to filing his motion: (a) if Plaintiff files his motion before January 31, 2021, Defendants will have 180 days to respond; (b) if Plaintiff files his motion on or after January 31, 2021, Defendants will have 90 days to respond. In either instance, this allows Defendants adequate time for class-related discovery so long as unforeseen further COVID-related delays do not arise.

Ensuring ample time for class-related discovery remains critical. Plaintiff's Complaint alleges an unprecedented class comprising more than 320 million putative class members, 99% of all Americans. Faced with such an unprecedented putative class, simple justice and fair process require that Defendants be afforded the opportunity for orderly discovery related to Rule 23 issues.

There are many issues that will need exploration in discovery and by experts before a motion for class certification can be adequately briefed. The Complaint alleges little about Plaintiff except that he is a long-time firefighter with PFAS of some unidentified sort in some unidentified concentration in his blood due to his work and possibly other exposures. There are, however, thousands of different types of PFAS and many more PFAS-containing products manufactured by different Defendants at different times—and some, for example, never manufactured PFOS or PFOA. Some Defendants have never manufactured any PFAS at all. Discovery is thus essential to determine whether the type of PFAS allegedly in Plaintiff's blood is traceable to any particular Defendant's products. While we continue to maintain that the mere presence of a chemical in Plaintiff's blood cannot be the basis of a claim, it is unquestionable that a blood-based theory of action cannot be predicated on a chemical that is not in his blood. Further, if the specific type of PFAS identifiably arose from Plaintiff's work as a firefighter (including the use of gear claimed to be a potential source of PFAS), it would place him in a substantially different posture than putative class members who lack that type of PFAS or who lack a firefighter's alleged work exposures. Even considering the issue of PFAS identification and provenance (which is but one subset of the issues necessary for briefing), and particularly considering the size and breadth of the proposed class, Defendants will need answers to interrogatories, and then Plaintiff's medical and employment records from third parties, and then likely depositions as well as additional medical information in order to respond to a motion for class certification.

Plaintiff's stated desire to be able to file a motion for class certification almost immediately—before any of this discovery takes place—is acceptable only if Defendants are given a schedule that is realistic given these discovery tasks, the COVID-environment, and the stakes involved. We hope that further extensions will not be needed, but we all understand that the nature of this virus may affect the schedule going forward.

We consequently request, on behalf of all Defendants, that the pretrial order specify that Defendants have 180 days to file their response to Plaintiff's class-certification motion, assuming reasonable cooperation in discovery and no further disruptions from the COVID-19 crisis, if Plaintiff files his motion before January 31, 2021, or 90 days to respond if Plaintiff files on January 31, 2021 or thereafter. We are available for a telephone conference at the Court's pleasure to discuss any part of our proposal.

Respectfully submitted,
/s/ Theodore M. Grossman
JONES DAY

cc: Counsel of Record

EXHIBIT

C-148

Taft/

425 Walnut Street, Suite 1800
Cincinnati, OH 45202-3957
Tel: 513.381.2838 | Fax: 513.381.0205
taftlaw.com

ROBERT A. BILOTT
513.357.9638
bilott@taftlaw.com

May 22, 2020

VIA ELECTRONIC MAIL
Chambers of the Honorable Edmund A. Sargus, Jr.
Chambers of the Honorable Elizabeth A. Preston Deavers
Sargus_Chambers@ohsd.uscourts.gov; Deavers_Chambers@ohsd.uscourts.gov

Re: Plaintiff's Letter Briefing on the Timing of Class Certification
Hardwick v. 3M Company, et al., No. 2:18-cv-1185 (S.D. Ohio)

Your Honors:

Pursuant to the Court's April 30, 2020 Preliminary Pretrial Order (ECF No. 156), Plaintiff Kevin D. Hardwick provides the following letter briefing outlining his position on the timing of his motion for class certification. Mr. Hardwick would like to file his motion for class certification as early as possible. Mr. Hardwick is amenable to establishing an outside deadline for filing the motion. But, he opposes Defendants' proposal (reaffirmed during the parties' May 18, 2020 telephone conference) that he be required to wait until February 1, 2021, or the start of any other "filing window," to submit his motion.

Allowing Mr. Hardwick to promptly file his motion as soon as he is ready will prevent unnecessary delay and facilitate the timely resolution of this case. Mr. Hardwick filed this case on October 4, 2018. Under Defendants' proposed timeline, Mr. Hardwick would not be permitted to file his motion for class certification until more than 28 months after bringing this lawsuit. There is no reason for Mr. Hardwick to wait until next February to file his motion for class certification, if he is ready to file before then.

Defendants contend that permitting Mr. Hardwick to file "an early motion" could "disrupt[] orderly discovery efforts." (Rule 26(f) Report at Page ID 1407, ECF No. 147.) As Defendants admit, however, the "proper timing of the class certification motion depends in part on the scope and breadth of discovery." (*Id.*) Because Mr. Hardwick believes he may require little, if any, additional discovery to support his motion, there is no reason to artificially delay the filing date.

Defendants assert that they require Mr. Hardwick's blood test results and several other discrete pieces of information to respond to the motion for class certification. Defendants have not explained, however, why it will take over eight months (until next February) to obtain this limited discovery from one named plaintiff. Nor have Defendants explained why their purported

need for discovery should prevent Mr. Hardwick from filing *his* motion. To the extent that Defendants actually require discovery to respond to Mr. Hardwick's motion, Defendants can seek that discovery after Mr. Hardwick has filed his motion and Defendants will actually have a better idea of what more narrowly-tailored information they will actually need to respond. The Court's Preliminary Pretrial Order provides Defendants with 90 days to file their opposition brief(s). That is more than enough time for Defendants to obtain whatever discovery they believe they need to oppose the motion.

Further, Defendants' purported concern about disrupting "orderly discovery efforts" rings hollow given Defendants' repeated efforts since the start of this case to delay discovery. After the oral argument on Defendants' motions to dismiss, the undersigned contacted defense counsel about holding the Rule 26(f) conference. Defendants refused, asserting that it was premature to confer before the Court ruled on the motions. On October 15, 2019, after the Court denied the motions to dismiss, the undersigned again contacted defense counsel about holding the Rule 26(f) conference. On October 25, 2019, nearly a month after the Court denied the motions to dismiss, Defendants proposed December 17 and 19, 2019, as potential dates to hold the conference. Only after the undersigned suggested raising the issue with the Court did Defendants agree to hold the conference on November 14, 2019. Mr. Hardwick provided Defendants with a draft Rule 26(f) report and a proposed protective order on December 12, 2019. Defendants did not respond to the draft Rule 26(f) report until January 9, 2020, and Defendants waited another week, until January 16, 2020, to provide their proposed version of the protective order. Because of Defendants' delays, the parties did not file their Rule 26(f) report until February 19, 2020. Prohibiting Mr. Hardwick from filing his motion for class certification until February 2021 would not disrupt discovery; it would simply advance Defendants' continuing efforts to delay this case.

Mr. Hardwick's proposal not only avoids delay but also comports with the controlling case law and Rule 23's plain language. Rule 23(c)(1)(A) directs the Court to decide class certification "[a]t an early practicable time after a person sues or is sued as a class representative." The Sixth Circuit, in turn, has stated that a court should defer a decision on certification pending discovery only where "the existing record is inadequate for resolving the relevant issues." *In re Am. Med. Sys., Inc.*, 75 F.3d 1069, 1086 (6th Cir. 1996) (quoting *Chateau de Ville Prods., Inc. v. Tams-Witmark Music Library, Inc.*, 586 F.2d 962, 966 (2d Cir. 1978)). Thus, whenever Mr. Hardwick believes the record is adequate to resolve the relevant issues, and believes he has the materials sufficient to support class certification under the applicable law, he should be free to move for such certification at that time. If Defendants then actually need further discovery to respond, they can obtain any needed discovery within the 90-day time frame for responding to the motion.

Mr. Hardwick respectfully requests, therefore, that the Court not impose any artificial delay to the date when he can first file his motion for class certification and allow Mr. Hardwick to file his motion as soon as he believes he is able.

Respectfully,

/s/ Robert A. Bilott
Robert A. Bilott
Counsel for Plaintiff

RAB:sk

EXHIBIT

C-149

The Knowledge Remedy

Alexandra D. Lahav*

This Article explains how common law judges can respond to situations in which a public good that is a necessary predicate for determining liability does not exist. To bring a products liability or environmental harm case, plaintiffs must prove that the product or chemical has a propensity to injure people and that it injured them. But studies demonstrating these facts are too costly for plaintiffs to fund. In many mass tort cases, it is in the defendant's interest not to conduct studies of the risks associated with chemicals or medical devices and, even when conducting such studies, it is in the defendant's interest to limit or manipulate research to avoid findings that their products pose a danger to consumers. Government would be the natural producer of such studies, but it does not fund or conduct enough of them. As a result, even if a plaintiff was injured by a toxin or product, where the defendant chose to hide its head in the sand rather than test, she cannot prove this was the case. She may lose even where there is evidence the defendant engaged in misconduct to prevent or hide research into its products. This Article proposes a second-best solution to this problem: a knowledge remedy which requires a defendant found to have engaged in misconduct to fund independent studies into what risks its products impose.

* Matina S. Horner Distinguished Visiting Professor, Radcliffe Institute for Advanced Study; Ellen Ash Peters Professor, University of Connecticut School of Law. This paper was largely written while on fellowship at the Radcliffe, and I am grateful to that program for its support. I am also grateful to Oren Bar-Gill, Lynn Baker, Bob Bone, Molly Brady, Jake Bronsther, Sam Bray, Maureen Carroll, Erik Encarnacion, John Goldberg, Greg Keating, J.J. Prescott, Margo Schlanger, Peter Siegelman, and Henry Smith for helpful comments that improved the paper considerably.

Introduction

Around 1996, the animals around Earl Tennant's farm started dying.[1] His once healthy herd came down with mysterious illnesses.[2] Cows' and calves' teeth turned black, they developed tumors, and lost significant amounts of weight although they were well fed.[3] In a few years, the herd was depleted. It wasn't just the cows. Woodland animals—deer and rabbits—were found dead on the property.[4] He had a suspicion about what was causing all these deaths: the creek on his farm. The family had sold some land to DuPont years before. The company used that land, which abutted the farm, as a landfill.[5] The creek foamed; Tennant suspected there was something in the water. As it turned out, the company was illegally dumping toxic waste, specifically what was then an obscure chemical called ammonium perfluorooctanoate (sometimes called APFO/PFOA or C8), into the landfill, and this toxin was getting into the water, running through the creek, and killing the cows, wildlife, and, as later became clear, people.[6] Not only was the chemical deposited in Tennant's landfill, it was being dumped into the Ohio River and silently poisoning thousands. But nobody knew this until it was unearthed as part of a lawsuit involving Earl Tennant's cows.

1. ROBERT BILOTT WITH TOM SHRODER, EXPOSURE: POISONED WATER, CORPORATE GREED, AND ONE LAWYER'S TWENTY-YEAR BATTLE AGAINST DUPONT 5 (2019).
2. *See id.* at 5, 40 (describing the inexplicable deaths of Tennant's "top-shelf" herd).
3. *Id.* at 5, 27.
4. *Id.* at 5.
5. *Id.* at 6.
6. *Id.* at 50–51, 53.

Tennant filed his private nuisance suit against DuPont in 1999.[7] At the time, he didn't know about C8. All he had was his own deduction that there was something wrong with the water coming out of the creek. He knew that it foamed,[8] that the animals all drank from it,[9] and that it abutted the landfill.[10] And he knew that in the past the creek had not foamed, and the animals had been healthy.[11] It took many months of civil discovery for his lawyer to learn of the existence of C8, in part because of DuPont's delays and prevarications, which are sadly pretty typical in this type of litigation.[12]

A big part of DuPont's resistance to discovery was that while the suit was pending in 2000, the EPA was investigating the use of this chemical.[13] The chemical's manufacturer, 3M, announced that it would cease making the chemical without explanation, but the reason appears to be EPA pressure.[14] DuPont was engaged in damage control with the EPA around this chemical, which at that point was unregulated, while it defended the Tennant lawsuit.[15] As Tennant's lawyer, Robert Bilott, explained:

> With federal regulators already sniffing around about PFOS, the last thing DuPont needed was anyone giving EPA any reason to have concerns about PFOA. They certainly wouldn't want EPA to know that a landfill containing PFOA was suspected of making hundreds of cows—and maybe some humans—very, very sick.[16]

This was a classic case of regulatory failure. The EPA did not know about this toxin, did nothing to regulate it, and the company wanted to keep it that way.[17] The chemical was useful and profitable.[18] It was a surfactant that was used to make Teflon, one of DuPont's best-selling products.[19] When personal injury cases were ultimately brought, people did find out about the toxin from the EPA, but only because an EPA official mailed them a letter from a lawyer describing the risks.[20] That lawyer was Robert Bilott.[21]

---

7. *Id.* at 29, 33–34.
8. *Id.* at 3–4.
9. *Id.* at 5.
10. *Id.* at 6.
11. *Id.* at 3–5.
12. *Id.* at 59–60, 66–67.
13. *Id.* at 54.
14. *Id.* at 52.
15. *Id.* at 54–55.
16. *Id.* at 54. PFOS is a chemical similar in composition to C8 and created by 3M. Because the two chemicals are similar, a regulatory problem for manufacturers using PFOS was likely to become a regulatory problem for those using C8 as well. *Id.* at 53.
17. *Id.* at 54.
18. *Id.*
19. *Id.* at 53–54.
20. *Id.* at 126–27.
21. *Id.*

The EPA itself had not studied the toxin. As the case progressed, it appears that the company was able to influence state regulators enough so they declared that there was no connection between the C8 in the water and disease and that the high amounts of C8 in the local drinking water were safe, although they were significantly higher than the level DuPont itself had suggested.[22]

It is also an example of the judicial branch, through common law adjudication, filling in a hole left by regulators. Bilott filed personal injury cases following his discovery of the toxin in the water supply.[23] These were certified as a class action seeking clean water and a medical monitoring program.[24] In the end, the plaintiffs got something much better. Their lawyers obtained a settlement fund to filter the water and, as importantly, to conduct independent research on the health effects of C8.[25] They used the results of that independent analysis to bring personal injury suits that are being litigated as these words are written.[26] These neutral studies determined which types of cancer were reliably linked to C8 and which were not, allowing plaintiffs with personal injuries to prove general causation in their follow-on tort suits.[27]

The story of Robert Bilott's discovery of DuPont's wrongdoing and his fight for justice for those injured has been published as a book and made into a movie.[28] The last part of the story, in which the plaintiffs received money from the defendant to conduct scientific studies, is what this Article is about. What Bilott negotiated is a knowledge remedy, a type of remedy that has not been recognized in legal scholarship but has played, and likely will continue to play, an important role in American law.

Because the United States does not adhere to the precautionary principle, many chemicals, toxins, and other products are introduced to the public with minimal study.[29] This is meant to spur innovation, but it also imposes costs on the people who end up being unwitting test subjects. If

22. *Id.* at 158–59, 163.

23. *Id.* at 137.

24. *See id.* at 144–47 (describing the plaintiffs' concern about the quality of the water and their interest in studies that would analyze the toxicity of the chemical).

25. *Id.* at 241–45.

26. *Id.* at 312–13.

27. *Id.* at 307, 331–33.

28. *See generally id.*; DARK WATERS (Focus Features 2019).

29. For an example of the precautionary principle applied in the context of environmental law, see U.N. Conference on Environment and Development, *Rio Declaration on Environment and Development*, U.N. Doc. A/CONF.151/26/Rev. 1 (Vol. I), annex I, at 6 (June 1992). The U.N. Conference on Environment and Development proclaimed that "[w]here there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." *Id.*

studies were funded by the government, evidence might be produced that would show a product is harmful, and it would be regulated and pulled from the market. But public funding is decreasing. If the law required companies to test their products before use or even after introduction to the market, and this mandate was reliably enforced, harmful products would be fewer. But there is no such legal rule. Instead, people rely on the tort system to fill the gaps where regulation fails.

Where there is weak regulation and little public knowledge, the residual system for mitigating and compensating for harm is the tort system. But without government or privately funded studies, causation in complex cases like the one against DuPont is difficult, perhaps impossible, to prove. Yet studies are too expensive for individuals or even groups to fund. And they take too long, potentially waiting out a statute of limitations and leaving plaintiffs without a viable cause of action. If a causal connection cannot be proven, regulation is never put in place and people are exposed to dangerous substances and suffer illnesses and loss of productivity that could be avoided.

Where regulation is lax and there is insufficient funding for the government to study the toxic effects of the chemicals, products, and pharmaceuticals that permeate our daily lives, a knowledge remedy is appropriate. A knowledge remedy requires the defendant to pay for the production of knowledge about the harm it is alleged to have caused. This remedy is what Bilott obtained for his clients, although nobody called it that. Indeed, the knowledge remedy has never been recognized as such, although it has a long history. This Article describes that remedy and explains its importance in today's legal landscape: a decidedly second-best world where regulation is limited, public study is infrequent, and potentially harmful products are everywhere. The contribution here is twofold. First, this is the first time the knowledge remedy has been conceptualized as a kind of remedy in legal scholarship, although courts have previously recognized it without giving it a name. Second, the Article explains the conditions for awarding this remedy and evaluates its benefits and costs.

The Article begins by describing the knowledge remedy using two examples involving toxic torts in which it was used: the case of DuPont and C8 in West Virginia and the case of a polluting aluminum plant in Oregon. It also describes a current case that might be well suited to such a remedy: lawsuits involving Roundup, an herbicide alleged to cause cancer. Part II describes the antecedents of the knowledge remedy, the accounting and medical monitoring, and concludes that it is part of a recognized remedial tradition. Part III describes when a knowledge remedy is appropriate and how it ought to be administered in mass tort litigation, including how to distinguish the knowledge remedy from discovery orders and how it intersects with preclusion doctrine. Part IV considers normative arguments in favor of and against the knowledge remedy. The knowledge remedy is

admittedly a non-ideal solution. But so long as regulation is lax and government funding is limited, it is a necessary one.

I. The Knowledge Remedy

The knowledge remedy is a remedial order in which the court requires a wrongdoer to pay for the production of new information. This Part describes two past instances of the knowledge remedy and how they played out. It demonstrates that the knowledge remedy is a viable way for courts to address situations where there are both strong indicia of wrongdoing and genuine but preventable scientific uncertainties. In these two examples, as appears to be the situation often enough, the uncertainty is in part a product of a company's failure to study the effects of the pollutants or products that are alleged to cause injury.[30] In the last subpart, this Part considers the application of the knowledge remedy to a current case: the litigation against Monsanto alleging that the herbicide Roundup is carcinogenic.

A. DuPont

Having already introduced the DuPont story, this subpart considers what happened to create the innovative and useful knowledge remedy in that case. The reader will recall that an initial property (nuisance) suit against the company led to the discovery that DuPont was disposing of a toxic chemical known as C8. As it turned out, the chemical was not only being dumped into the landfill abutting Tennant's ranch, but also into the Ohio River, contaminating the drinking water.[31]

Discovery in the Tennant lawsuit led to information about the risks of C8, in particular that the company had become aware in the 1980s that C8 was a potential carcinogen.[32] Among the evidence discovered was that 3M, which supplied C8 to the company, had warned of potential hazards and that the company had transferred pregnant women (or those who might become pregnant) out of work areas where they would be in contact with C8.[33] In

30. This is a form of preventable scientific uncertainty. Preventable scientific uncertainty is the problem that it may be in a defendant's interest not to test a product or chemical in order to avoid failure-to-warn claims later. *See* Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 CORNELL L. REV. 773, 776, 780 (1997) (distinguishing between two types of scientific uncertainty, one of which, preventable uncertainty, is the result of a lack of reasonable investment).

31. BILOTT WITH SHRODER, *supra* note 1, at 67–68.

32. *Id.* at 80–81.

33. *Id.* at 228–29.

meetings, the company discussed the potential risks but decided not to study them further because C8 was so useful and lucrative.[34]

These findings led to a second lawsuit, a class action filed in 2001 by residents of a neighboring town who claimed that C8 contaminated their drinking water.[35] The state court certified a class action of medical monitoring claims.[36] It also issued an injunctive order requiring DuPont to pay for blood testing to determine the levels of the chemical in class members' blood. This order was appealed and reversed on the grounds that it was an improper discovery order.[37] As this Article will show, that was a category error on the appellate court's part. What the district court initially ordered, which tracks substantially what the parties ultimately agreed to, was actually a kind of remedy.

The appellate court held that the company was not obligated to pay for the plaintiffs to prove their claims. It viewed the plaintiffs' request as asking "that the burden of the expense of gathering evidence, testing for the presence of C–8, be shifted to [D]uPont. In a creative manner, the plaintiffs are simply asking the circuit court to shift the costs of the discovery process . . . ."[38] This, the appellate court held, violated the general principle that each party pay for the costs of proving their own case. In other words, it rejected the knowledge remedy as nothing more than a misunderstanding about who pays for discovery.

The reason that the appellate court erred was that the appropriate category of plaintiff's request was not procedural but remedial. In the case before it, the plaintiffs had already demonstrated that the defendant had engaged in misconduct. The plaintiffs had shown evidence that DuPont had released C8 into the water and that C8 was linked to the death of Tennant's animals.[39] The question should have been whether a knowledge remedy was appropriate at that juncture in the litigation, not whether this was an attempt at cost-shifting. Later developments in the case proved how appropriate such a remedy would have been.

Thankfully, the appellate court's decision is not where the case ended. DuPont's regulatory situation worsened. The EPA began a more serious investigation and sued the company.[40] There were news reports of the danger

34. *Id.* at 189–92; Roy Shapira & Luigi Zingales, *Is Pollution Value Maximizing? The DuPont Case* 7 (Nat'l Bureau of Econ. Research, Working Paper No. 23866, 2017), https://www.nber.org/papers/w23866.pdf [https://perma.cc/RJ9U-ERYQ].

35. Shapira & Zingales, *supra* note 34; Leach v. E.I. Du Pont de Nemours & Co., No. 01-C-608, 2002 WL 1270121, at *1 (Cir. Ct. W. Va. Apr. 10, 2002).

36. *Leach*, 2002 WL 1270121, at *8–18.

37. State *ex rel.* E.I. Dupont De Nemours & Co. v. Hill, 591 S.E.2d 318, 326–27 (W. Va. 2003).

38. *Id.*

39. BILOTT WITH SHRODER, *supra* note 1, at 110.

40. *Id.* at 231.

of Teflon, including a 20/20 segment featuring the son of a DuPont employee who had suffered significant and disfiguring birth defects, most likely as a result of exposure to C8 in the womb.[41] Furthermore, the West Virginia courts permitted damning emails sent by DuPont's lawyers to be used by the plaintiffs in litigating the case because the company had waived the attorney–client privilege.[42] In the emails, the lawyers lamented that DuPont was continuing to pollute the local water despite knowing that C8 was bio-persistent and risked injury to the community.[43] "Our story is not a good one," the lawyers had written in these internal emails, "we continued to increase our emissions into the river in spite of internal commitments to reduce or eliminate the release of this chemical into the community."[44] With the tide turning against it, DuPont settled the claims. That settlement included both remediation of the water supply and, importantly for our purposes, an independent study to determine the carcinogenicity of C8.[45] This agreement, approved by the court under the state equivalent of Federal Rule 23(e), is a knowledge remedy.[46]

The settlement committed DuPont to spend $107 million on a community study of the effects of C8.[47] The company agreed that if the study found a "probable link" between C8 and human disease, it would concede general causation in subsequent litigation.[48] It would also pay for medical monitoring.[49] If the study found no probable link between cancer and C8 exposure, then class members would release future tort claims.[50]

The first step was the collection of blood samples and information from about 69,000 residents who might have been affected.[51] A panel of independent researchers was appointed by the community and DuPont to

41. *Id.* at 218–19, 221–22.

42. *Id.* at 235.

43. *Id.*

44. *Id.*

45. *Id.* at 24.

46. Although this was a private settlement, it could also be characterized as a judicial order because it required judicial approval.

47. Laura Hall et al., *Litigating Toxic Risks Ahead of Regulation: Biomonitoring Science in the Courtroom*, 31 STAN. ENVTL. L.J. 3, 20 (2012).

48. Christine H. Kim, *Piercing the Veil of Toxic Ignorance: Judicial Creation of Scientific Research*, 15 N.Y.U. ENVTL. L.J. 540, 575 (2007) (citing Joint Motion for Preliminary Approval of Settlement at 5, Leach v. E.I. DuPont de Nemours & Co., No. 01-C-608, at 5 (Cir. Ct. W. Va. Nov. 22, 2004)). This ended up being a significant source of controversy in subsequent litigation. *See In re* E. I. Du Pont De Nemours & Co. C8 Pers. Injury Litig., No. 2:13-CV-170, 2016 WL 659112, at *4 (S.D. Ohio Feb. 17, 2016) (discussing the *Leach* settlement agreement).

49. Hall et al., *supra* note 47, at 21.

50. *In re E. I. Du Pont De Nemours & Co. C-8 Pers. Injury Litig.*, 2016 WL 659112, at *4.

51. *The Science Panel*, C8 SCIENCE PANEL, http://www.c8sciencepanel.org/panel.html [https://perma.cc/T2YS-TBCW].

determine the causal link between C8 and a list of cancers. They first collected existing studies and then conducted their own studies of the effects of C8.[52] These scientists found a link for a subset of the listed diseases.[53] Approximately 3,500 personal injury lawsuits were filed by individuals, consolidated in the Southern District of Ohio, and bellwether trials were scheduled.[54] Some of these cases were tried, others settled.[55] As of this writing, jury trials are scheduled through 2020.[56]

Without the studies, it would have been nearly impossible for the plaintiffs to prove their case. The studies they were able to conduct, involving perhaps a few hundred individuals, would likely be insufficient proof in a trial. The evidence that C8 caused birth defects came from a group of seven female workers exposed to the substance at DuPont, two of whose children suffered birth defects.[57] This was too small a sample to draw any conclusions about causation. Only a governmental study or one funded by the company could have provided the type of evidence needed to prove general causation, to spur cleaning the water and prevent further exposure of innocent people to this dangerous chemical.

A study such as the one ultimately obtained in the *DuPont* case is a public good.[58] Everyone is better off if a study is done, but no individual actor

---

52. *C8 Science Panel Studies*, C8 SCIENCE PANEL, http://www.c8sciencepanel.org/study.html [https://perma.cc/YX48-L3FK]. The panel went on to explain:

> No single epidemiologic study is sufficient to determine whether C8 adversely affects health. The Science Panel designed a series of complementary studies to generate necessary data for its work in assessing the probable links between C8 and disease. These studies began in late 2006 and are completed, with results summarised in the Probable Link reports and presented in detail in scientific articles . . . .

Id. For a list of the published studies, see *C8 Study Publications*, C8 SCIENCE PANEL, http://www.c8sciencepanel.org/publications.html [https://perma.cc/7PB7-STH4].

53. For a list of the probable link evaluations of the C8 Panel, see *C8 Probable Link Reports*, C8 SCIENCE PANEL, http://www.c8sciencepanel.org/prob_link.html [https://perma.cc/XFP7-4ZMF].

54. *See In re* E. I. Du Pont De Nemours & Co. C-8 Pers. Injury Litig., Case Management Order No. 20, 204 F. Supp. 3d 962, 965 (S.D. Ohio 2016) (describing the court's setting of the bellwether trials).

55. *See*, *e.g.*, Kris Maher & Cameron McWhirter, *DuPont Settlement of Chemical Exposure Case Seen as 'Shot in the Arm' for Other Suits*, WALL ST. J. (Feb. 13, 2017), https://www.wsj.com/articles/dupont-chemours-settle-teflon-chemical-exposure-case-for-671-million-1486987602 [https://perma.cc/CH5S-MDT8] (describing large-scale settlement of C8 suits); Jess Mancini, *DuPont Planning to Appeal $50M Verdict in C8 Case*, PARKERSBURG NEWS & SENTINEL (Mar. 5, 2020), https://www.newsandsentinel.com/news/local-news/2020/03/dupont-planning-to-appeal-50m-verdict-in-c8-case/ [https://perma.cc/574K-LCQ6] (describing verdict in C8 trial).

56. *In re* E.I. Du Pont de Nemours & Co. C-8 Personal Injury Litigation, Case Management Order No. 28, Case No. 13-md-2433 (S.D. Ohio Jan. 7, 2019).

57. BILOTT WITH SHRODER, *supra* note 1, at 177.

58. A public good in economics is defined as a good that is nonrivalrous and nonexcludable. The type of scientific information described here can be used by many without being consumed (as

has the incentive to create it. The reason everyone benefits is that if C8 is bio-persistent and harmful, DuPont can take steps (or be required to take steps) to prevent its release into the environment, saving people's lives, the cost of litigation, and the need to pay damages.[59] If C8 is not carcinogenic, DuPont will not be sued and thus save the cost of litigation, the cost of paying damages, and the cost of preventing its release into the environment. But DuPont had no incentive to conduct such a study because it calculated that it was better off hiding the potential carcinogenicity or hoping that C8 was not injurious.[60] The plaintiffs had an interest in conducting such a study but insufficient funding to conduct such a study before obtaining damages. Furthermore, they lacked access to the specific technology needed (the only laboratory able to test for C8 in the blood was controlled by DuPont). There is an open question as to whether they might have received financing based on the amount of money they were likely to obtain in damages. If they had, this would probably have depleted a significant amount, if not all, of their recovery. What this says about the tort system is that it relies on external sources of information to function. Damages compensate for the harm caused, but they may not be sufficient to pay for *proving* that harm.

B. Harvey Aluminum

In 1958, Harvey Aluminum opened a plant in Oregon. The plant was located in an agricultural community that grew stone fruit, mostly cherries.[61] In the next couple of years, it became clear to the orchard owners that the smoke emitted from the plant was destroying their livelihood as the cherry crops decreased.[62] The orchardists filed a lawsuit in federal court in 1961 seeking abatement of the emissions.[63] But like many toxic tort cases, they faced an uphill battle proving the Harvey plant's emissions were the cause of the problems with the harvests. There were no extant studies, for example, and the government was not going to fund any.[64] The orchardists were

---

is the nature of information) and people cannot be excluded from using it. At least once a court orders it released. As a matter of observation, it is not created by the market. Yet it promotes social welfare. The best producer of such information is the government. Because of regulatory failure and market failure, the courts are left with the problem articulated in this Article.

59. I am assuming here that if damages were correctly calculated, they would exceed the value of using C8 to produce Teflon.

60. *See generally* Shapira & Zingales, *supra* note 34 (concluding that pollution was value maximizing for DuPont in this case based on available data about its profits from use of C8 and the costs of regulatory fines and tort suits).

61. Douglas A. Kysar & Conor Dwyer Reynolds, *Of Coase and Cherries: Risk Regulation Among Neighbors in Wasco County*, at 2 (Apr. 23, 2019) (unpublished manuscript) (on file with author).

62. *Id.* at 11.

63. *Id.* at 21–22.

64. *Id.* at 23.

funding research themselves, through a league they had created, but with dwindling crop yield it was difficult to raise money for expensive research.[65] A trial was held in 1963, and cross-examination of the plant's experts revealed that they found new damage to the crops after the emissions began and that it was likely that the plant's emissions were causing injury to the crops.[66] It was in the remedial phase that the fight that is relevant to our inquiry occurred.

Harvey Aluminum's claim was that it was financially impossible, perhaps even technically impossible, for it to abate the emissions.[67] Plaintiffs' experts described other aluminum plants in the United States that had abatement systems in place.[68] The judge agreed with the plaintiffs, ordering the Harvey plant to install cell hoods and use electrostatic precipitators to limit emissions.[69] The company appealed and, on appeal, introduced new testing evidence indicating that it had abated some of the problem. As it turned out, this representation was false because the tests the company submitted were done during a one-month period when the plant was shut down.[70] The appellate court allowed a new trial and, in a rather unusual move, ordered that the defendant would pay for it.[71]

While the case was proceeding to trial on remand, the plaintiffs discovered that a different abatement system was in use in Germany, and this new technology was better at abating the chemical emissions that injured their crops than that available in the United States.[72] The District Court ordered "advances" to the plaintiffs to pay for them to research state-of-the-art abatement systems in aluminum plants in various countries in Europe.[73]

As in the DuPont litigation, the court styled the knowledge remedy as a discovery order. But, in fact, it was a knowledge remedy, one that was a predicate to determining what appropriate injunction the court should ultimately order. It was not a discovery order because it did not require the defendant to produce information already in its possession, but rather to pay for the creation of *new* information.[74] After five years of litigation and

65. *Id.* at 24.

66. *Id.* at 25, 32–33.

67. *Id.* at 33–34.

68. *Id.* at 35.

69. *Id.* at 36.

70. *Id.* at 47. The plaintiffs were ultimately able to prove this fraud on the court, but only after a second round of discovery.

71. *Id.* at 42.

72. *Id.* at 44–45.

73. *Id.* at 45–46.

74. There is a line-drawing problem between discovery and remedy in these examples, and indeed in knowledge remedies more generally. However, although there may be some overlap between these categories, as there is in much of law, at their core they are different from one another

scientific research, the company and the growers reached a consent decree that would create an independent body to set air quality standards with which the company would comply.[75]

Also like the DuPont case, the company did not have an incentive before the suit to research pollution-mitigation options. The incentives seem to have run the other way, as the company first resisted claims that its emissions caused injury, then affirmatively tried to hide and misrepresent the extent of its emissions. In the face of this type of wrongdoing, a knowledge remedy that imposed on the defendant the cost of researching mitigation systems was appropriate. This is especially true if the court was loath to order closure of the plant, and the plant owners, counting on this fact, preferred to take the small risk that they would be shut down to perhaps obtain the greater benefit of having to make no or minimal investments in mitigation systems. The fact that the company was willing to misrepresent its emissions indicates that, like DuPont, it preferred to hide the problem and risk greater sanctions. The reason for this must be that it calculated the likelihood of sanctions as very low. Absent the court's discovery of this misconduct and subsequent remedial order, this evaluation was probably correct.

C. Monsanto

Dewayne "Lee" Johnson was a groundskeeper for a California school district. One of his tasks was to spray herbicide, probably to kill the poison oak that grows so well in that part of the country.[76] The herbicide he used was Roundup, one of the most powerful weed killers available and part of a modern miracle created by Monsanto, the agricultural giant. Using Monsanto's herbicide-resistant seeds, farmers can spray acres of land and only kill the weeds, leaving the crops standing. But Roundup isn't used only by farmers, but also by states, counties, towns, and even individuals in their backyards.

Lee Johnson got a cancer diagnosis of non-Hodgkin's lymphoma after a few years of working as a groundskeeper. He had been doused at least once in Roundup, and started experiencing skin problems, including painful lesions.[77] His claim at trial was that Roundup caused his cancer. There was

---

because the discovery order requires a party to produce information it already has, whereas a remedial order requires a party to do something in addition to what it has already done.

75. Kysar & Reynolds, *supra* note 61, at 48.

76. Sam Levin, *The Man Who Beat Monsanto*, GUARDIAN (Sept. 26, 2018), https://www.theguardian.com/business/2018/sep/25/monsanto-dewayne-johnson-cancer-verdict [https://perma.cc/X3KW-YEJD].

77. *Id.*

some evidence that glyphosate may be carcinogenic.[78] But non-Hodgkin's lymphoma can have any number of causes. And it is a relatively common cancer. More than 70,000 people received this diagnosis in the United States in 2019.[79]

The studies on the relationship between glyphosate, the active ingredient in Roundup, and this cancer are incomplete. Some studies have shown an association, but these can be rebutted with others. The trouble is, Monsanto stood in the way of much of the possible research into the carcinogenicity of glyphosate. At trial, plaintiffs presented evidence of early animal studies, dating from 1983, which were indicative of carcinogenicity (although not at all definitive).[80] There was evidence of ghostwriting—where a company will assist in an author's work without being acknowledged, a practice which is considered unethical—as well as evidence of attempts to influence scientists.[81] And there was evidence of regulatory capture. An EPA administrator told a Monsanto executive that he should "get a medal" for preventing further inquiry into the safety of the product.[82]

Epidemiologists disagreed. There were studies on both sides. And ultimately the plaintiffs were able to overcome evidentiary hurdles and the dueling experts who testified at trial. Johnson won close to $39 million in compensatory damages and $250 million in punitive damages.[83]

There have been many more lawsuits. In October 2019 Bayer AG, Monsanto's parent company, reported that more than 42,000 suits had been filed against it in connection with Roundup.[84] There have also been two more

78. The International Agency for Research on Cancer (IARC) published a report on March 20, 2015 classifying glyphosate as probably carcinogenic to humans. *Some Organophosphate Insecticides and Herbicides*, 112 IARC MONOGRAPHS ON THE EVALUATION OF CARCINOGENIC RISKS TO HUMANS, at 398 (2015), monographs.iarc.fr/ENG/Monographs/vol112/mono112-10.pdf [https://perma.cc/T284-RFMV].

79. *Lymphoma - Non-Hodgkin: Statistics*, CANCER.NET (Aug. 2019), https://www.cancer.net/cancer-types/lymphoma-non-hodgkin/statistics [https://perma.cc/WPF9-BVVL].

80. An internal EPA memo from 1985 stated: "Under such circumstances, a prudent person would reject the Monsanto assumption that Glyphosate dosing has no effect on kidney tumor production." Memorandum by Herbert Lacayo to Reto Engler (Feb. 26, 1985) (on file with author).

81. Danny Hakim, *Monsanto Emails Raise Issue of Influencing Research on Roundup Weed Killer*, N.Y. TIMES (Aug. 1, 2017), https://www.nytimes.com/2017/08/01/business/monsantos-sway-over-research-is-seen-in-disclosed-emails.html [https://perma.cc/ATB9-AXXU].

82. *See* Email from Daniel Jenkins, Monsanto, to William Heydens, Monsanto (Apr. 28, 2015, 9:33 AM) (on file with author) (quoting an EPA official who said that "[i]f I can kill this I should get a medal").

83. Holly Yan, *Cancer Patient Who Was Awarded $289 Million in Monsanto Trial Says He'll Take $78 Million Instead*, CNN (Nov. 1, 2018, 11:51 AM), https://www.cnn.com/2018/11/01/health/monsanto-plaintiff-accepts-lower-award/index.html [https://perma.cc/S474-NV8C]. As noted in the article, the verdict was remitted to $78 million, an outcome that Monsanto is currently appealing. *Id.*

84. Adrian Croft, *As Roundup Lawsuits Pile Up By the Thousands, Bayer Remains Defiant*, FORTUNE (Oct. 30, 2019, 11:24 AM), https://fortune.com/2019/10/30/roundup-lawsuits-bayer-defiant/.

verdicts, both multimillion losses for Monsanto.[85] In a second case in California state court, the jury awarded $2 billion in punitive damages.[86] In the wake of these developments, Monsanto's parent company Bayer announced that it would spend $5.6 billion to study the potential carcinogenicity of the herbicide Roundup.[87]

In the meantime, Monsanto is appealing the verdict in Johnson's case. As part of that appeal, there has been an organized campaign to paint this case as one of "junk science." Amicus briefs were filed by California doctors and high-powered biotechnology companies like Genentech.[88] Even the Environmental Protection Agency filed briefs supporting the company in a related appeal.[89]

The Roundup cases are not about junk science or juror misunderstanding of science. Rather, they are examples of preventable scientific uncertainty, and it appears from the punitive damages verdicts that the jury found this uncertainty was created by Monsanto itself. There are three ways to deal with this type of uncertainty. One is to place the burden of the costs of damages on the defendant, in light of conclusion that the absence of evidence was found to be the defendant's wrongdoing. Another is to place the costs of damages on the plaintiffs, in light of the continuing uncertainty. A third way is to impose a knowledge remedy, requiring independent studies of glyphosate to promote greater understanding. While there will never be perfect knowledge, given the ethical limitations on conducting double-blind clinical studies on the effects of exposure, studies could produce greater consensus in the epidemiologic community.

---

85. A second state court jury in *Pilloid v. Monsanto* awarded $55 million in compensatory and $2 billion in punitive damages. Both amounts were remitted by the judge. Tina Bellon, *In Roundup Case, U.S. Judge Cuts $2 Billion Verdict Against Bayer to $86 Million*, REUTERS (July 25, 2019, 8:25 PM), https://www.reuters.com/article/us-bayer-glyphosate-lawsuit/in-roundup-case-u-s-judge-cuts-2-billion-verdict-against-bayer-to-86-million-idUSKCN1UL03G [https://perma.cc/M8CS-ABN4].

86. *Id.*

87. Douglas Busvine & Ludwig Burger, *Bayer to Invest $5.6 Billion in Weedkiller Research to Help Reputation*, REUTERS (June 14, 2019, 12:52 AM), https://www.reuters.com/article/us-bayer-glyphosate/bayer-to-invest-5-billion-euros-in-weedkiller-research-idUSKCN1TF0I1 [https://perma.cc/UH2F-ZCZY].

88. Brief for Genentech, Inc. as Amici Curiae Supporting Defendant and Appellant, Johnson v. Monsanto Co., No. A155940 & A156706 (Cal. Ct. App. Aug. 30, 2019); Brief for California Medical Association et al. as Amicus Curiae Supporting Neither Party, Johnson v. Monsanto Co., No. A155940 & A156706 (Cal. Ct. App. Aug. 30, 2019); Brief for California Farm Bureau Federation as Amici Curiae Supporting Appellant, Johnson v. Monsanto Co., No. A155940 & A156706 (Cal. Ct. App. Sept. 3, 2019).

89. An EPA brief was filed in the Ninth Circuit appeal. Jacob Bunge & Timothy Puko, *Trump Administration Backs Bayer in Weedkiller Court Fight*, WALL ST. J. (Dec. 20, 2019), https://www.wsj.com/articles/epa-backs-bayer-in-weedkiller-court-fight-11576879555 [https://perma.cc/CP28-AU4D].

There surely will be more studies now that the litigation has made glyphosate and Roundup the subject of sustained media attention. But if the courts cut off liability, the results of that consensus will come too late for plaintiffs. And if the courts sustain liability, the results will be too late for Monsanto. One solution that could be respectful of the jurors' decision would be to impose an interim knowledge remedy. It cannot be denied that this outcome would impose significant costs on plaintiffs such as Johnson, who has already endured a trial and is dying but would be forced to wait to receive compensation. Nevertheless, such a knowledge remedy is a better alternative as compared with immunity from liability given the evidence of misconduct.

II. Historical Antecedents

This Part describes two historical antecedents of the knowledge remedy, demonstrating that the knowledge remedy is not a new judicial invention but has ancient roots. Its origins lie in difficulties of proof suffered by certain groups, usually as a result of information asymmetries. The difference between the original knowledge remedy, the accounting, and its twenty-first century use is that the accounting is a purely private remedy. It benefits only the individual before the court who has been cheated by a fiduciary. By contrast, the knowledge remedy produces a public good, one which benefits the entire community or even the nation.

A. The Accounting

The accounting is perhaps the oldest knowledge remedy.[90] A party who fears they have been cheated would first bring an action in equity as a bill for discovery and second, if the discovery showed a claim for money could lie, a follow-on suit for breach of contract, breach of fiduciary duty, or some other similar writ, as appropriate.[91] It is hard to understand why this would have been so without recalling the basic structure of the court system in this early period. Under the regime when equity and law were separate jurisdictions, the request for discovery in cases that might otherwise have been brought at law were brought in equity as a bill for discovery.[92] This is because at that time, exchange of information before trial was not available in actions at

90. *See* 1 JOSEPH STORY, COMMENTARIES ON EQUITY JURISPRUDENCE §§ 689–90 (9th ed. 1866) (discussing the bill of discovery); Christopher C. Langdell, *A Brief Survey of Equity Jurisdiction* (vol. 4), 2 HARV. L. REV. 241, 250–60 (1889) (discussing the equitable remedy of an accounting).

91. Langdell, *supra* note 90, at 243–51. Although Langdell claims that the action for an account is an action at law, *id.* at 251, according to Story, it is an action in equity. STORY, *supra* note 90. Story's explanation appears to be the correct one in light of the known history of equity.

92. STORY, *supra* note 90, at § 689; *see also id.* § 64*k* (discussing the concurrent jurisdiction of equity and law in actions for discovery); *id.* §§ 67, 69 (listing "account" as among potential equity claims).

law.[93] Yet the plaintiff might not be able to make her case without discovery, so the solution was to allow a separate bill for discovery under the cause of action known as an accounting.

The purpose of an accounting is to force the defendant to create information that will then be used to obtain compensation, if any is due. Over time, the accounting evolved into a cause of action that, after the merger of law and equity, may be brought in any court, even if discovery is otherwise available.

An illustrative example of a modern accounting arises in the context of a consignment agreement. In one modern case, Zaki Kulaibee Establishment (Zaki) entered into a contract with Airspares Network to sell a large shipment of aircraft parts on consignment.[94] The deal went sour, and Zaki alleged that Airspares "breached the contract by selling Zaki's parts without properly accounting for the sales proceeds, charging Zaki for inflated storage expenses, and failing to return the parts after Zaki terminated the consignment agreement."[95] During the course of conduct between the parties, Airspares provided only summary information to Zaki and refused to provide more detailed information about such things as how many and which parts were sold or proof of expenses.[96]

The case initially proceeded as a breach-of-contract and consignment claim seeking money damages, but after over two years of discovery, the plaintiff was unable to obtain the information needed to make its case.[97] It was denied access to the warehouse to count inventory, and Airspares refused to provide the underlying documentation supporting its deduction of expenses from sales of the consigned parts.[98] Before trial, Airspares moved for summary judgment; Zaki responded that it should not have to take at face value the defendant's claims that all the calculations of sales and expenses were accurate and that an accounting was necessary.[99] Without an accounting, it could not prove its breach-of-contract claim.[100]

The district court held that Zaki was not entitled to an accounting because it had an adequate remedy at law through its breach of contract and

93. AMALIA KESSLER, INVENTING AMERICAN EXCEPTIONALISM: THE ORIGINS OF AMERICAN ADVERSARIAL LEGAL CULTURE, 1800–1877, 68–71 (2017) (describing forms of process for common law versus equity courts in New York).

94. Zaki Kulaibee Establishment v. McFliker, 771 F.3d 1301, 1302–03 (11th Cir. 2014).

95. *Id.* at 1303.

96. *Id.* at 1304.

97. *Id.* at 1306, 1308–09.

98. *Id.* at 1308–09.

99. *Id.* at 1309.

100. *Id.*

conversion claims.[101] The Court of Appeals disagreed.[102] It held that under Florida law, an accounting is available "in cases of especially complicated or mutual accounts, where a fiduciary relationship existed between the parties, and in cases where discovery was required."[103] Discovery being available in all cases under the modern procedural rules, it explained, the two remaining grounds for an accounting were the relevant considerations.[104] The court held that Airspares had agreed to act as a fiduciary in taking on the consignment relationship and

> because a consignee is not tasked with *holding* the property entrusted to him and returning the *same property* to the consignor at a later date, but rather with *disposing* of the property and returning *something else* (the fungible proceeds of the sales of the goods) to the consignor, the need to impose a fiduciary obligation to account becomes particularly apparent.[105]

A core duty of the consignee is to provide a true and accurate account of its stewardship of the goods in question.[106] Because the company had admitted that it had not accounted for its stewardship of the goods, an accounting was an appropriate remedy.[107]

The usual discovery mechanisms were not enough, the court explained, because "[d]iscovery simply could not provide the kind of close, consistent, and knowledgeable oversight necessary to procure that information from a sophisticated party who both possessed all the relevant details and had substantial motivation to frustrate the discovery process."[108] Appointing a special master, armed with the coercive power of the court itself, was the appropriate remedy.[109]

The accounting remedy teaches us four things. First, an accounting is a form of knowledge remedy aimed at obtaining information from the defendant to give to the plaintiff utilizing court oversight. Second, an accounting may be a preliminary remedy on the way to a monetary award. Third, it was considered equitable in the early history of American law. Fourth, as we saw in the DuPont and Harvey Aluminum examples, there is

---

101. *Id.*
102. *Id.* at 1316.
103. *Id.* at 1311.
104. *Id.*
105. *Id.* at 1312.
106. *Id.* at 1313.
107. *Id.*
108. *Id.* at 1315.
109. *Id.* at 1315–16; *see also* FED. R. CIV. P. 53(a)(1) (authorizing court to appoint a master to perform an account or resolve a difficult computation of damages); 9C CHARLES ALAN WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE AND PROCEDURE § 2605 (3d ed. 2008) (describing the practice of referring matters of account to a master as a "very traditional and fairly frequent use of a master").

an overlap between knowledge remedies and the discovery process, but still a knowledge remedy can be distinct from that process in the appropriate case.

B. Medical Monitoring

Medical monitoring was originally a prejudgment remedy aimed at maintaining the status quo ante in personal injury litigation when litigation was drawn out and the plaintiffs' condition was deteriorating. The case that first recognized what is now often referred to as "medical monitoring" was a D.C. Circuit decision by Judges Starr, Bork, and Mikva, *Friends for All Children, Inc. v. Lockheed Aircraft Corp*.[110] The names are important because two of these judges are generally considered to be politically conservative. The case involved Vietnamese orphan children who were being airlifted to the United States. "Fifteen minutes after takeoff a locking system failed, causing the aft ramp and cargo doors to fall off the aircraft. The interior compartments of the plane thereupon suffered an explosive decompression and loss of oxygen."[111] The pilot turned the plane around and attempted a crash landing, "[b]ut on impact the aircraft shattered into four large pieces and countless fragments. Almost all the orphans and attendants in the cargo compartment of the aircraft were killed."[112] In the end, 149 children (mostly infants) "in the aircraft's troop compartment survived."[113]

The infants' representative sued the Lockheed Aircraft Corporation, the plane manufacturer. Over a period of years, there was significant procedural maneuvering, ending with a number of bellwether trials. In most of these, the plaintiffs won high six-figure verdicts.[114] Still, it looked like there would be no global settlement. Ultimately it turned out that Lockheed and the United States Air Force had failed to produce evidence that had been requested in discovery, including photographs taken immediately after the crash.[115] After this, most of the cases settled, leaving only seventy cases involving foreign plaintiffs. The litigation at that point had been ongoing for seven years and would likely take many more. The children were getting older. This group of plaintiffs sought what they called an "injunction pending litigation" to require

110. 746 F.2d 816 (D.C. Cir. 1984).

111. *Id.* at 819.

112. *Id.*

113. *Id.*

114. *Id.* at 820. The plaintiffs won three cases, resulting in verdicts of $400,000, $1,000,000, and $500,000. *Id.* The defendants won once but the verdict was set aside by the district court. *Id.* That case was subsequently retried and resulted in plaintiffs' third win. *Id.* All in all, there were four trials for the three plaintiffs.

115. *Id.* at 821.

Lockheed to pay for diagnosis and treatment of the neurological development disorder they believed was caused by the crash.[116]

The district court granted a preliminary injunction requiring diagnostic testing of the children.[117] The central reason was irreparable damage; as time passed, with a diagnosis lacking, the children's prognoses would be worse.[118] The court ordered Lockheed to put money in a fund, which would be disbursed based on a voucher system that allowed the company to contest each award.[119]

On appeal, the company's main argument was that without proof of physical injury, there was no cause of action, and therefore the court ought not to have issued a preliminary injunction. The D.C. Circuit rejected this argument. It held that the provisional diagnostic remedy was consistent with the purposes of tort law: deterrence and compensation.[120] It distinguished this case from cases rejecting a cause of action for being put "at risk" of an injury because those cases involved speculative proof, whereas in this case, the defendant's negligence was not speculative.[121] The only issue was whether that negligence *caused* an injury, which the diagnostic test could determine.[122] The need for a diagnostic test, therefore, was proximately caused by the defendant's failure to take appropriate care in the maintenance of the plane.

The theory of medical monitoring is that the underlying wrong involves a failure on the defendant's part to take adequate care (negligence) or producing and marketing a defective product.[123] Often it is justified by a special relationship between the plaintiff and the defendant, such as that of privity from the purchase of a product.[124]

---

116. *Id.* at 818–19.

117. *Id.* at 821–22.

118. *Id.* at 822–23.

119. *Id.* at 823.

120. *Id.* at 824–25.

121. *Id.* at 826 ("In the absence of physical symptoms, emotional distress caused by potential risk may also be thought too speculative to support recovery.").

122. *Id.* at 825–26. The court analogized this to a motorbike accident caused by a driver running a red light. The victim was required to undergo expensive diagnostic tests. The driver's action was clearly negligent; therefore, requiring the driver to pay for the testing was appropriate. *Id.* at 825.

123. As a side note, it is not clear that what is commonly referred to as strict liability for defective products can also be characterized as something more akin to negligence. That debate is beyond the scope of this Article. *See, e.g.*, Douglas A. Kysar, *The Expectations of Consumers*, 103 COLUM. L. REV. 1700, 1711 n.44 (2003) ("[T]he strict liability of product injury law never has been truly strict . . . [r]ather, in addition to duty, causation, and damages, products liability plaintiffs always have been required to make some showing of inadequacy with regard to the manufacturer's product, if not its conduct."); David G. Owen, *Defectiveness Restated: Exploding the "Strict" Products Liability Myth*, 1996 U. ILL. L. REV. 743, 744 (1996) (arguing that "the reasonableness standard . . . is simply negligence, wrapped in a strict liability shroud").

124. John C.P. Goldberg & Benjamin C. Zipursky, *Unrealized Torts*, 88 VA. L. REV. 1625, 1706 (2002).

The remedy for this breach is that the defendant will pay for periodic medical checkups for the plaintiff, and the greatest area of dispute about the propriety of this remedy seems to be that it is often requested when the plaintiff's injury has yet to materialize.[125] This fact makes medical monitoring somewhat controversial because of the proposition that traditionally tort law has required a physical injury for a claim to lie.[126] The reason for the request for medical monitoring absent physical injury is uncertainty with respect to the plaintiffs' injury. The question in this type of case is not preventable scientific uncertainty, but rather the factual uncertainty of disease development and the prevention of harm due to the delay in litigation outcomes. Some people will be unlucky and will develop a disease as a result of exposure; others will be lucky, but nobody knows before the fact in which group they will be.

John Goldberg and Benjamin Zipursky have argued that medical monitoring can be justified as a species of negligence based on breach of a "duty owed by one who has created a dangerous condition that renders another in peril and hence in need of affirmative aid."[127] Consider this in light of the Supreme Court's decision in *Metro-North Commuter Rail Co. v. Buckley*.[128] Buckley was a Metro North employee who sued Metro North claiming that he was exposed to asbestos during the course of his employment and sought damages for emotional distress and the cost of future medical checkups.[129] Notably, until that point, his medical checkups had not found any evidence of injury from asbestos exposure, although they might have in the future. The Supreme Court rejected the proposition that there was a negligence claim for emotional distress. It also rejected the claim for a lump sum payment for medical monitoring absent injury and remanded the suit, leaving open the possibility of periodic payments for medical monitoring.[130] The Court recognized that Buckley "*has* suffered wrong at the hands of a negligent employer."[131] But it rejected the award of a lump sum for this

125. *See* Victor E. Schwartz et al., *Medical Monitoring—Should Tort Law Say Yes?*, 34 WAKE FOREST L. REV. 1057, 1058 (1999) ("Plaintiffs in such cases seek post-exposure, pre-symptom recovery for the expense of periodic medical examinations to detect the onset of physical harm.").

126. *Id.* at 1059 (citing WILLIAM L. PROSSER, HANDBOOK ON THE LAW OF TORTS § 54, at 330–33 (4th ed. 1971) for the proposition that it is a fundamental principle of tort law that "a plaintiff cannot recover without proof of a physical injury").

127. Goldberg & Zipursky, *supra* note 124, at 1710; *see also* Nicole Rosenkrantz, Note, *The Parent Trap: Using the Good Samaritan Doctrine to Hold Parent Corporations Directly Liable for Their Negligence*, 37 B.C. L. REV. 1061, 1065 (1996) (describing a ruling where the Court held one owes a duty of reasonable care to those who rely on the individual's actions).

128. 521 U.S. 424 (1997).

129. *Id.* at 427. Buckley sued under "FELA, a statute that permits a railroad worker to recover for an 'injury . . . resulting . . . from' his employer's 'negligence.'" *Id.*

130. *Id.* at 444.

131. *Id.* at 443.

purpose because it was concerned with the risk of enabling too much litigation, which would diminish recovery for those actually injured in favor of recovery for those, like Buckley, who were not yet injured.[132]

The idea that instead medical monitoring is a form of affirmative aid, owed to Buckley by virtue of the fact that he was put in danger by his employer when it allowed him to be exposed to asbestos despite regulatory requirements that employees be protected explains why ongoing payments for medical monitoring might be appropriate while a lump sum would not.[133] It also explains why medical monitoring was a viable remedy in cases like *Friends for All Children*. There were good indicia that Lockheed had placed the children in danger as a result of a fault in its plane, and this danger would be harder and harder to mitigate as the litigation continued. Medical monitoring as an interim remedy would provide the aid needed as a result of the danger that Lockheed had created for the children.

Goldberg and Zipursky's reading that the medical monitoring cases require a special relationship different than that of a purchaser and seller is probably too narrow. Early cases demonstrate that a duty is owed in situations where a manufacturer puts a dangerous product in circulation that would harm unsuspecting consumers. This duty could give rise to a knowledge remedy, much as it could give rise to a compensatory remedy. In the 1852 case *Thomas v. Winchester*,[134] for example, the New York Court of Appeals held that a manufacturer of medicinal extracts who had mislabeled the poison Belladonna as dandelion extract had a duty to the patients who were prescribed the drug.[135] "Nothing but mischief like that which actually happened could have been expected from sending the poison falsely labeled into the market;" stated the court, "and the defendant is justly responsible for the probable consequences of the act."[136]

There remains some dispute about whether medical monitoring is a remedy or an independent cause of action. Some courts have recognized medical monitoring as an independent cause of action,[137] while others have

132. *Id.* at 443–44 The Court went on to say that they were
> more troubled than is JUSTICE GINSBURG by the potential systemic effects of creating a new, full-blown, tort law cause of action—for example, the effects upon interests of other potential plaintiffs who are not before the court and who depend on a tort system that can distinguish between reliable and serious claims on the one hand, and unreliable and relatively trivial claims on the other. *Id.*

133. Goldberg & Zipursky, *supra* note 124, at 1710.

134. 6 N.Y. 397 (1852).

135. *Id.* at 410.

136. *Id.*

137. Wood v. Wyeth–Ayerst Labs., 82 S.W.3d 849, 855 (Ky. 2002) (stating medical monitoring requires showing of actual, physical injury).

treated it as a remedy.[138] There are plausible arguments both ways, just as there is an argument that an accounting in equity is an independent cause of action rather than a remedy for an action in contract.

The medical monitoring remedy is a knowledge remedy aimed at obtaining information that does not yet exist about plaintiffs' health. It can be a preliminary remedy that may come within or be followed by a personal injury suit. Like the accounting, it is understood as equitable in nature. Also like an accounting, it is preceded by a showing of some breach of duty to take care of another. Finally, the rationale that some have proposed for allowing this remedy, particularly that the defendant has been shown to increase the plaintiffs' risk of harm and therefore is responsible to aid him, echoes the events described in both the DuPont and Harvey Aluminum cases.

C. Civil Rights Compliance

A third, less controversial example of the knowledge remedy in action occurs in civil rights litigation. These tend to be cases of information asymmetry, like the accounting, where the plaintiffs cannot prove the wrong without access to information only available directly from the defendant. The collection of this information might be described as a public good, although not necessarily in the sense that economists use the term. Rather, it is a public good because government compliance with the law is necessary to the general common welfare.[139]

In 1999, several black and Latino residents of the City of New York sued the City, alleging that in high crime areas, the police were stopping individuals without reasonable suspicion in violation of the Fourth Amendment.[140] They alleged that the police were racially profiling, stopping black and Latino men on the basis of their race and/or national origin rather

138. Sadler v. PacifiCare of Nev., 340 P.3d 1264, 1270 (Nev. 2014) ("[A] plaintiff may state a cause of action for negligence with medical monitoring as the remedy . . . .").

139. For a summary describing the philosophical concept of the common good, see generally Hussain Waheed, *The Common Good*, *in* THE STANFORD ENCYCLOPEDIA OF PHILOSOPHY (Edward N. Zalta ed., 2018), https://plato.stanford.edu/archives/spr2018/entries/common-good/ [https://perma.cc/J98J-84JH]. *See also* JOHN LOCKE, SECOND TREATISE ON GOVERNMENT 6 (C. B. Macpherson ed., 1980) (stating that the political power to defend the laws is "to be directed to no other *end*, but the *peace*, *safety*, and *public good* of the people"). For more on problems with governmental compliance and an overview of compliance issues in the context of administrative agencies, see generally Nicholas R. Parrillo, *The Endgame of Administrative Law: Governmental Disobedience and the Judicial Contempt Power*, 131 HARV. L. REV. 685 (2018).

140. Daniels v. City of New York, 198 F.R.D. 409, 411 (S.D.N.Y. 2001). An earlier lawsuit on the same subject had been filed and dismissed on technical grounds. *See* Nat'l Cong. for Puerto Rican Rights v. City of New York, 75 F. Supp. 2d 154, 158 (S.D.N.Y. 1999), *on reconsideration in part*, 191 F.R.D. 52, 52–54 (S.D.N.Y. 1999) (denying motion to dismiss in part, granting as to organizational standing).

than on any articulable suspicion,[141] a policy that was popularly referred to as stop-and-frisk. The Southern District of New York certified a class action for injunctive and declaratory relief in 2001.[142]

The City entered into an agreement with the plaintiffs in 2003, which was approved by the judge under Federal Rule of Civil Procedure 23(e).[143] This agreement required the City to adopt a policy on racial profiling, to engage in quality control over stops consistent with that policy, and, importantly for our purposes, to collect data on stops and frisks on an ongoing basis.[144] For every stop the police officer was supposed to fill out a form, called a UF-250.

These forms were in use in the NYPD before the litigation, apparently as early as 1986, but the requirement to fill them out was not rigorously enforced until around 1997.[145] Even then, they were not routinely filled out.[146] As part of the agreement, the NYPD would make sure forms were filled out and the information contained in UF-250 forms would be digitized and collected in a database.[147] The NYPD would provide the plaintiffs' counsel with a quarterly report of the data, a report that was to be provided within six months of the end of each quarter.[148] The settlement did not explain how plaintiffs would use this information, did not impose any standards or goals for UF-250 data, and did not impose any penalties for trends and patterns revealed in the database.[149]

Disputes over the reporting from the UF-250 database did not arise until 2007.[150] The exact parameters of the dispute are not so important here, except

---

141. *Daniels*, 198 F.R.D at 411.

142. *Id.* at 412, 422.

143. Daniels v. City of New York (*Daniels II*), No. 99 Civ. 1695 (SAS), 2007 WL 2077150, at *1 (S.D.N.Y. July 16, 2007).

144. Stipulation of Settlement at 5–6, 8–9, *Daniels II*, No. 99 Civ. 1695(SAS), 2007 WL 2077150 (S.D.N.Y. July 16, 2007), https://www.clearinghouse.net/chDocs/public/PN-NY-0010-0001.pdf [https://perma.cc/UBU2-9HMN]; *Daniels II*, 2007 WL 2077150, at *1.

145. *See* N.Y. STATE OFFICE OF THE ATT'Y GEN., REPORT ON STOP AND FRISK 65 (2000), https://ag.ny.gov/sites/default/files/pdfs/bureaus/civil_rights/stp_frsk.pdf [https://perma.cc/G63C-B2AW] ("Completion of the UF-250 form has been required since 1986. In 1997, however, Commissioner Safir declared filing the UF-250's 'a priority' that should be 'rigorously enforced.'").

146. *Id.* at 72.

147. *Daniels II*, at *1.

148. *Id.*

149. *Id.* The settlement did clarify that

> [t]he Agreement, however, does not include any provisions regarding plaintiffs' use or analysis of the UF-250 data. Nor does the Agreement contain any remedies or obligations regarding any trends or patterns reflected in the UF-250 database. Moreover, the Agreement does not require any specific outcomes and makes no specific assurances with respect to the supervision, monitoring and training of NYPD officers with regard to the Racial Profiling Policy.

Id.

150. *Id.* at *2.

insofar as the plaintiffs alleged that the defendants did not provide information on the court-ordered schedule, and the defendants responded both that the plaintiffs had not sought the information for several years and thus slept on their rights.[151] It was also alleged that the decentralized approach to collecting the information and the need for manual data entry delayed the database.[152] The court was charged with determining whether the City had failed to comply with the agreement that the parties had reached with respect to the data and what remedy should issue. Ultimately, the judge ordered specific performance of the information production on a schedule proposed by the plaintiffs.[153]

The database information was ultimately released to the plaintiffs. This data was used by the New York Attorney General's office to produce a 2013 report on racial disparities in stops,[154] by the ACLU in periodic reports of racial disparities in New York City policing,[155] and by subsequent plaintiffs suing the NYPD for racial profiling.[156]

The use of the knowledge remedy to ensure governmental compliance with constitutional mandates is similar to the knowledge remedy in the Harvey Aluminum case, although there the court order impacted a private rather than public actor. This use of the knowledge remedy further supports the position that the knowledge remedy can be a predicate to further litigation seeking an injunction or monetary award if damages can be proven, and a knowledge remedy may be issued based on allegations of wrongdoing rooted in the duty to comply with legal directives.

III. Applying the Knowledge Remedy

This Part lays out the predicates for applying the knowledge remedy. It describes how judges might apply the knowledge remedy equitably and how

151. *Id.*

152. *Id.*

153. *Id.* at *4.

154. N.Y. STATE OFFICE OF THE ATT'Y GEN., A REPORT ON ARRESTS ARISING FROM THE NEW YORK CITY POLICE DEPARTMENT'S STOP-AND-FRISK PRACTICES 5 (2013), https://ag.ny.gov/pdfs/OAG_REPORT_ON_SQF_PRACTICES_NOV_2013.pdf [https://perma.cc/QP4R-XE54]. Notably, it appears that this data was obtained directly from the NYPD, not through the *Daniels* plaintiffs or the ACLU. *See id.* at 2 (describing data but not mentioning the *Daniels* litigation).

155. The New York Civil Liberties Union put the quarterly reports provided by the NYPD online. To look at the reports, see NEW YORK CIVIL LIBERTIES UNION, *NYPD Quarterly Reports*, https://www.nyclu.org/en/nypd-quarterly-reports [https://perma.cc/AZ8K-6SZN]. In addition, they produced publications such as a "Stop and Frisk Fact Sheet." NEW YORK CIVIL LIBERTIES UNION, *Stop and Frisk: Report on 2011 Findings*, https://www.nyclu.org/sites/default/files/stopandfrisk-factsheet.pdf [https://perma.cc/C5FA-7GX3].

156. That lawsuit was filed in 2008. Floyd v. City of New York, No. 08 CIV. 1034(SAS), 2008 WL 4179210, at *1 (S.D.N.Y. Sept. 10, 2008). A Rule 37 motion for production of UF-250 data was granted. *Id.*

they ought to distinguish it from civil discovery. Finally, it considers the preclusive effect of the knowledge remedy.

A. Predicates for Imposing a Knowledge Remedy

The knowledge remedy is appropriate when the plaintiff has already shown indicia of harm at the defendant's hands and the inability to meet their burden of proof as a result of information asymmetries ordinarily (but not always) caused by the defendant's misconduct. In all the cases we have seen so far, evidence of some wrongdoing on the part of the defendant was presented to the court. Whether this evidence of wrongdoing was enough to trigger some kind of remedial action is the larger question, one that can only be resolved on a case-by-case basis. Further, in each of these cases, there were also problems of proof that were the result of information asymmetries. In at least some of them, production of these remedies was a public good—they were in no one's interest to produce but in society's interest to have.

These qualities dictate the two requirements of a knowledge remedy: (1) evidence of wrongdoing, such as creating a dangerous condition putting the plaintiff in need of aid, and (2) problems of proof that are usually the result of a combination of information asymmetry and the lack of incentives of any of the participants in the litigation to create such information although its production would be a public good.

B. Equitable Flexibility and Court Oversight

The knowledge remedy is an equitable remedy, similar to an injunction, and therefore has the flexibility to come in a variety of forms: a fund to pay for medical monitoring, independent epidemiologic research, research into new technologies, or the production of information by the defendant in-house where appropriate. This flexibility also permits the courts leeway in determining whether the information asymmetries or a public-goods problem, combined with the indicia of harm presented by plaintiffs, warrant this form of remedy.

Equitable remedies such as the knowledge remedy generally share three characteristics.[157] They require performance of an action (or omission) rather than direct payment of money, court management of the process by which the knowledge is produced, and flexibility in relation to the plaintiff's injury rather than providing a one-for-one response to that injury.

First, equitable remedies compel action or inaction by a party, in contradistinction to legal remedies that generally compel monetary compensation.[158] The knowledge remedy is not compensatory, in the sense

157. *See* Samuel L. Bray, *The System of Equitable Remedies*, 63 UCLA L. REV. 530, 551 (2016) (arguing that equity is a system).

158. *Id.* at 553 (describing the remedial aspects of equity and their role in the legal system).

that it is not a backward-looking attempt to make the plaintiff whole. But neither is it wholly like a traditional injunction, in the sense that it is not intended to prevent a defendant from taking a particular action or requiring the defendant to take such an action.

Often the knowledge remedy will require a payment, but that payment is aimed at the production of knowledge or information that did not previously exist and does not compensate the plaintiff for her injuries. For example, when a court orders an accounting, which is to say an inquiry into the defendant's handling of money or property, the idea is that in the end this information will be used to determine how much the defendant owes the plaintiff.[159] An order requiring the defendant to pay that amount follows. But that second order is a function of a different cause of action: breach of fiduciary duty.

In sum, a knowledge remedy requires the defendant to do something, but often this payment comes in the form of paying money to an independent entity for a specific work product rather than a compensatory payment to the plaintiff that is meant to capture their harm. For example, the defendant might pay doctors for medical monitoring, or pay an independent researcher to study whether a toxin is carcinogenic, or pay for research into alternative technologies available in other countries.

Second, equitable remedies require some management or oversight of the defendant's performance of the court's order. While legal remedies rarely present problems of compliance, equitable remedies ordinarily present problems of "specifying, measuring, and ensuring compliance."[160] For example, decades of litigation over compliance followed school desegregation orders in the 1970s.[161] Knowledge remedies face similar problems of compliance in that the requirement can often be ongoing, produced over a period of years in the case of scientific studies; the parameters of a particular set of studies or agenda for research need to be set out in the initial order; and there will usually be a need for some kind of oversight, perhaps once the study is complete, or, depending on the disputes

159. *Id.* at 553–54 (citing *Wilde v. Wilde*, 576 F. Supp. 2d 595, 608 (S.D.N.Y. 2008) ("An equitable accounting requires two steps. First, upon a showing that an accounting is warranted, an interlocutory decree is issued requiring the fiduciary to make an accounting. Once the accounting is made, a second hearing is held to establish the final amounts owed to the principal.").

160. *Id.* at 563.

161. *See, e.g.*, Kimberly Jenkins Robinson, *Resurrecting the Promise of* Brown*: Understanding and Remedying How the Supreme Court Reconstitutionalized Segregated Schools*, 88 N.C. L. REV. 787, 802–04 (2010) (describing litigation to enforce desegregation); *see also* MICHAEL J. KLARMAN, FROM JIM CROW TO CIVIL RIGHTS: THE SUPREME COURT AND THE STRUGGLE FOR EQUALITY 6–7 (2004) (providing a pessimistic history of the developments after *Brown*); MARTHA MINOW, IN BROWN'S WAKE: LEGACIES OF AMERICA'S EDUCATIONAL LANDMARK 1–4 (2010) (providing a more optimistic history).

between the parties, as it is ongoing. Determining the scope of study, as well as compliance with such a directive, are decisions that require the oversight characteristic of an equitable remedy.

Third, equitable remedies are flexible and not necessarily limited to returning the plaintiff to her rightful position, or at least can define the rightful position in such a way as to provide greater opportunity for the court to craft a remedy to solve complex structural problems.[162] There is a vigorous debate in the scholarship over whether judges overreached in the 1960s and '70s with remedies that were not aimed solely at the plaintiffs before them but rather at systemic institutional change. Some argue that the rightful position ideal is a limitation on judicial action.[163] Others dispute this claim, arguing that the proper approach to equitable remedies is a less constrained equitable discretion.[164] This latter argument is mostly made in the context of public law litigation. Because the knowledge remedy does not provide compensation for the plaintiff's physical injury, but instead remedies the plaintiff's lack of information caused by the defendant's wrongdoing, it is an equitable remedy in this sense. Rather than compensation, the knowledge remedy fills in holes created by the defendant's lack of care or the defendant's having put the plaintiff in danger.

While the knowledge remedy could be characterized as a form of injunction, there is one significant difference.[165] Unlike an injunction, the knowledge remedy does not require the defendant to do something to cure the harm that was caused to the plaintiff. Instead, it asks the defendant to pay to provide knowledge about how that harm might be cured, what has caused it, or what harm is occurring to the plaintiff on an ongoing basis. The costliness of the knowledge remedy, and its relative rarity, means that it is not a regularly available remedy like monetary remedies. Indeed, like an injunction, a knowledge remedy is exceptional.[166]

---

162. Bray, *supra* note 157, at 570.

163. DOUGLAS LAYCOCK, MODERN AMERICAN REMEDIES 235–36 (3d ed. 2002) (discussing the dispute over the purpose of injunctive relief and whether it is intended to place the plaintiff in the "rightful position" where she would have been absent the defendant's misconduct); *cf.* Samuel L. Bray, *Multiple Chancellors: Reforming the National Injunction*, 131 HARV. L. REV. 417, 471 (2017) (arguing that injunctions should be limited to the parties before the court and not for the benefit of third parties). While a knowledge remedy would be consistent with Bray's position on national injunctions, it would still benefit the plaintiffs before the court and third parties.

164. For a classic expression of the broad judicial role, see Abram Chayes, *The Role of the Judge in Public Law Litigation*, 89 HARV. L. REV. 1281, 1282 (1976).

165. For purposes of the class action rule, the knowledge remedy should be characterized as an injunction because it more closely resembles injunctive relief as compared with monetary relief. *See* FED. R. CIV. P. 23(b)(2) (allowing a class action if final injunctive relief is appropriate to the whole class).

166. In this sense a knowledge remedy is like an injunction. *Cf.* Samuel L. Bray, *The Supreme Court and the New Equity*, 68 VAND. L. REV. 997, 1037 (2015) (discussing the longstanding idea that injunctions are exceptional).

C. Relationship to Discovery

Many of the examples of the knowledge remedy in action show the courts confusing a knowledge remedy with discovery. Recall that in the DuPont case, the appellate court in West Virginia denied a knowledge remedy on the grounds that it was shifting the costs of discovery to the defendant impermissibly.[167] Indeed, the best argument against imposing the knowledge remedy is that it violates the American tradition of requiring each party to pay for the costs of litigation on her own. The problem with this narrative, as we have seen, is that the legal system often depends on publicly produced information in order for the plaintiff to prove her claim. Epidemiologic studies conducted by the government or using government funds for research, Centers for Disease Control and Prevention data, and regulations requiring legal actors to track certain data all enable plaintiffs to prove their case. None of these sources of information are paid for by the plaintiffs individually; largely because they are so costly, they would make bringing suit economically impractical.

However, the civil process used to enforce the law overlaps with its substantive and remedial requirements so that it is easy to confuse a knowledge remedy with civil discovery.[168] One of the jobs of the court imposing a knowledge remedy is to make this distinction. Discovery is a "show-me" process.[169] By contrast, a knowledge remedy is a requirement that the party being ordered to remedy a wrong create information that did not previously exist. In the accounting context, that means creating (or recreating) the accounting books with respect to transactions. The plaintiff could ask for evidence of these transactions in discovery, but if the defendant did not create them, then that request is a futile exercise. In other cases, knowledge creation may require medical studies, monitoring, or surveys. This should be expected to be a more onerous proposition than producing already extant information.[170] This is at the core of the concept of a *remedy*: requiring the defendant to right a wrong by producing information that did not previously exist.

---

167. State *ex rel.* E.I. Dupont De Nemours & Co. v. Hill, 591 S.E.2d 318, 326–27 (W. Va. 2003).

168. This is an old problem. Justice Joseph Story mentions this problem while discussing the difficulty in maintaining the boundary of equity jurisdiction with respect to the bill for relief and the bill for discovery in his COMMENTARIES ON EQUITY JURISPRUDENCE, *supra* note 90, at § 70. While modern procedural rules are ordinarily understood to be transsubstantive, there have in fact grown up a large number of practices that are specific to certain subject matter.

169. With apologies to the state of Missouri.

170. Although, of course producing information in discovery is also expensive in some subset of cases. Alexandra D. Lahav, *A Proposal to End Discovery Abuse*, 71 VAND. L. REV. 2037, 2049 (2018).

As we have already seen in the discussion of the accounting, during the early period in American law, in both equity and law, procedure was intertwined with substance. The claim asserted dictated the court, the procedure, and the remedy available. Today, these categories of substantive claim and procedure are understood to be separate. This is the result of a political project begun with the Field Code.[171] The project was to describe procedure as a kind of handmaiden of substance, a process that in itself did not dictate outcomes.[172] The purpose of characterizing procedure this way was to obtain lawyer control over that process and dampen controversy by making the subject more technocratic. One of the results of the project that did affect substance was the expansion of civil discovery. Prior to the Field Code, civil discovery, such as it was, was only available in equity.[173] The project of incorporating civil discovery into legal claims was completed with the Federal Rules of Civil Procedure which specifically permit discovery in all claims.[174]

In a regime where discovery is limited to certain types of claims in certain courts, it is easy to see how it is intertwined with the claim and the remedy available for that claim. The accounting is a perfect example. Recall that in *Zaki*, the court explained that an accounting was available "in cases of especially complicated or mutual accounts, where a fiduciary relationship existed between the parties, and in cases where discovery was required."[175] Why, the defendant asks in that case, is an accounting necessary when civil discovery was already available to the plaintiff? The court's answer is that even in light of the availability of civil discovery to all cases, the special circumstance of the fiduciary relationship in a consignment case requires an accounting.[176] Part of the thinking behind the rationale (that despite the availability of civil discovery an accounting is required) is the distinction between *creating* information and *showing* information.

To determine whether a knowledge remedy is appropriate, once the threshold showing that the plaintiff has been placed in danger by the defendant's conduct, the court must inquire into whether there is informational asymmetry or a public goods problem. This inquiry will overlap with the question of whether this information gap can be cured with discovery of information the defendant already *has* or whether it requires the

171. *See generally* KESSLER, *supra* note 93, at 152–199 (describing political and economic forces that drove procedural change).

172. *Id.* at 147.

173. *See* Stephen N. Subrin, *How Equity Conquered Common Law: The Federal Rules of Civil Procedure in Historical Perspective*, 135 U. PA. L. REV. 909, 919 (1987) (describing the historical usage of equity discovery processes before the enactment of the *Federal Rules of Civil Procedure*).

174. *See* FED. R. CIV. P. 26 (permitting broad discovery).

175. Zaki Kulaibee Establishment v. McFliker, 771 F.3d 1301, 1311 (11th Cir. 2014).

176. *Id.* at 1312.

defendant to produce *new* information. This poses some difficulties around the edges. For example, in an accounting, is the information needed to account for the consigned goods already in the defendant's possession, therefore properly understood as discovery? Or is this information that can only be produced under supervision, as occurred in *Zaki*, in which case a remedial order is required? Or suppose a defendant failed to comply with a regulatory mandate to retain certain employment information such as employee time spent donning and doffing protective clothing.[177] The determination of the time spent donning and doffing could be characterized as part of discovery, usually paid for by the plaintiff. But because the absence of information was caused by the defendant's failure to comply with the law, it could also be characterized as a knowledge remedy for which the defendant must pay.

Although a knowledge remedy may sometimes overlap with discovery, in general the distinction between information that the defendant has and information the defendant must create should be sufficient in the run of cases to determine whether the order is remedial rather than procedural and therefore not subject to the American rule that each party bear the costs of proving her own case.

D. Preclusion

The timing problem in awarding knowledge remedies is a serious one because the knowledge remedy is often a preliminary remedy to a damages action. The result is that the defendant may face two lawsuits, one seeking a knowledge remedy and the second seeking damages. For example, in the case of the accounting, the accounting itself is a predicate to the award of damages for breach of fiduciary duty or contract. As discussed earlier, however, only if the accounting reveals that the defendant acted wrongfully, by converting the property or otherwise violating its duty to the plaintiff, does the defendant have to pay. Similarly, the diagnosis and monitoring remedy in *Friends of the Children* was a prejudgment remedy that anticipated a final monetary remedy at the end of the litigation.

Yet the knowledge remedy may also be final. For example, medical monitoring is sometimes a final remedy.[178] In general, the knowledge remedy will be final in cases where monitoring and knowledge-production are expected to produce compliance with the law in themselves, rather than as a

177. Tyson Foods, Inc. v. Bouaphakeo, 136 S. Ct. 1036, 1043–45 (2016) (discussing how the company failed to keep records that would have proven or disproven plaintiffs' claim, permitting plaintiffs to present statistical evidence).

178. *See, e.g.*, Petito v. A.H. Robins Co., 750 So. 2d 103, 108 (Fla. Dist. Ct. App. 1999) (upholding medical monitoring as final remedy under Florida law).

predicate to later compensation. This latter case describes the *Daniels* situation, in which proof of racial profiling led to a remedy that included tracking for compliance purposes. When it was learned that the practice continued despite this remedy, a second lawsuit was brought.[179]

May the plaintiff bring a second claim against the same defendant if the production of knowledge indicates that there is further liability? This is a concern because the general rule in civil litigation is that one must bring all claims arising out of the same transaction or occurrence at once.[180] To bring some claims and not others is called "claim splitting" and is frowned upon in nearly all jurisdictions.[181]

Knowledge remedies need not be preclusive of subsequent monetary remedies arising out of the information obtained in the first suit, even with the principle against claim splitting in place. For example, medical monitoring has been held not to preclude a subsequent claim for personal injury.[182] This is often because the state will have adopted a discovery rule for the attachment of preclusive effect in tort. The plaintiff's claim only becomes viable when they have discovered their injury. In some jurisdictions, the law goes further and states that the cause of action accrues only when "the victim is aware of the injury or disease and of the facts indicating that a third party is or may be responsible."[183] In such jurisdictions, the medical monitoring case may be a precursor to subsequent personal injury litigations, as occurred in the DuPont case.

The DuPont case raises a second possibility, however. In jurisdictions where there is a discovery rule only, it may be that the plaintiff will not be able to file a subsequent suit if she knew of her injury but not the cause, even if that cause was discovered by a knowledge remedy. In the DuPont case, the parties' agreement permitted follow-on litigation. It may be that, in some cases, the court would have to retain jurisdiction in order to allow recovery once the information produced by the knowledge remedy is available.

---

179. *See* Floyd v. City of New York, No. 08 Civ. 1034(SAS), 2008 WL 4179210, at *1–2 (S.D.N.Y. Sept. 10, 2008) (describing history of rulings for *Daniels* settlement that led to more litigation).

180. *See* RESTATEMENT (SECOND) OF JUDGMENTS § 24 (AM. LAW INST. 1982) (describing transactional test to determination of claim for preclusion purposes).

181. *See id.* § 25 (stating that the claim-splitting rule in § 24 extinguishes plaintiffs' claims even if they are prepared for a second action).

182. *See Petito*, 750 So. 2d at 106 (holding "that plaintiffs in medical monitoring cases will not be precluded by the rule against splitting causes of action from bringing claims for whatever physical injuries they suffer if and when they arise").

183. Ayers v. Jackson TP., 525 A.2d 287, 300 (N.J. 1987). *But see* Sinclair v. Merck & Co., 948 A.2d 587, 593 (N.J. 2008) (describing subsequent limitations on the holding in *Ayers* in product liability cases brought under New Jersey statutory law).

The provision against claim splitting also does not apply to subsequent events.[184] As a result, individuals harmed by a continuing practice, as occurred after the *Daniels* litigation, for example, may use the information obtained in the first litigation in their subsequent suit about ongoing events.

IV. Evaluating the Knowledge Remedy

This Part considers the normative arguments in favor of and against a knowledge remedy. There are four main arguments favoring knowledge production as a remedial tool. First, the knowledge remedy fills a regulatory gap in cases where, due to agency capture or other failures of oversight, untested products or toxins enter the market and are alleged to injure people. Second, the knowledge remedy promotes the creation of the public good of knowledge production about the effects of products on the populace, a form of knowledge which past conduct demonstrates is not in the interests of manufacturers to create. Third, the knowledge remedy can also increase legitimacy of the judicial branch by avoiding accusations that the results of cases are based on so-called junk science. Fourth, as a regulatory mechanism, it may be a way for companies to avoid bankruptcy from litigation based on what turn out to be erroneous understandings of causation on the one hand, and an administrative requirement of preapproval of products and toxins before they are marketed, on the other.

There are also four main arguments against the knowledge remedy. First, the knowledge remedy delays recovery for the set of plaintiffs who would have won their lawsuits despite uncertainty. Second, one might argue that the knowledge remedy is really a new duty to test in disguise. Third, the knowledge remedy may promote claim splitting, thereby increasing the amount of litigation. Finally, the knowledge remedy may be an improper expansion of the judicial role to what Lon Fuller would have called "polycentric" disputes better handled by regulatory bodies.[185]

One additional set of arguments with respect to the knowledge remedy not addressed here involve its likely impact on primary conduct. That is, is the knowledge remedy socially optimal? I leave this question for another paper.

---

184. Media Rights Techs., Inc. v. Microsoft Corp., 922 F.3d 1014, 1022 (9th Cir. 2019) (quoting Stanton v. D.C. Court of Appeals, 127 F.3d 72, 78 (D.C. Cir. 1997)) ("Federal law is clear that post-judgment *events* give rise to new claims, so that claim preclusion is no bar." (emphasis added)).

185. Lon L. Fuller, *The Forms and Limits of Adjudication*, 92 HARV. L. REV. 353, 394–95 (1978).

A. Arguments in Favor

This subpart describes arguments in favor of the knowledge remedy.

1. Filling a Regulatory Gap.—As many of the cases described above illustrate, the knowledge remedy can fill a regulatory gap. In an ideal world, agencies would conduct studies on chemicals such as C8, would monitor emissions from plants such as the Harvey Aluminum plant in Oregon, and would maintain and review records of stops and frisks to make sure they were not conducted on a discriminatory basis. But as these cases illustrate, agencies can fall short in their oversight.

There are many reasons for such failure and it is beyond the scope of this Article to analyze them all. Sometimes, as in the DuPont case, the agency may simply be unaware of the existence of the chemical and does not consider testing it for that reason. Or as also occurred in the DuPont case, an agency may be influenced by the manufacturer to limit testing or announce the safety of a chemical about which it has little information. Other times the agency may be fooled by misconduct on the part of the company, as occurred when the Harvey Aluminum plant released testing data from a period when it was shut down to show lower emissions. Whatever the reason, the absence of regulatory oversight means that chemicals and products are not safety tested. The knowledge remedy fills this gap by requiring such testing.

The knowledge remedy is an incomplete gap-filler. It would apply where the company has acted wrongfully to endanger the plaintiffs, often by failing to test despite indicia of danger and exposing the population to the product, or by deliberately sowing scientific uncertainty in the face of emergent evidence of risk. But in cases where there are no indicia of danger, the company could not be required to pay for knowledge production. In such cases, only government testing or public funding of testing would be able to fill the gap.

2. Promotes Public Goods Creation.—A second benefit of the knowledge remedy is that it promotes the creation of a public good, which is to say it fosters information that benefits the public and which is not in the interest of those who can or would be expected to create it. For example, an analysis of the costs and benefits of the DuPont litigation from the company perspective showed that it was not in the interest of DuPont to study the carcinogenic effects of that chemical.[186] Indeed, given the benefits to the company of continuing to produce Teflon, and the costs of moving to a different chemical, it turns out that from a pure-profit point of view, the company decided not to conduct studies even after they had evidence of birth defects among female

186. Shapira & Zingales, *supra* note 34, at 14–20.

employees. That study concluded that it was value maximizing for DuPont to continue polluting because DuPont made more money over the period that it polluted than it ultimately paid out in liability.[187]

In a first-best world, studies of risk exposure from chemicals and products would be publicly funded. As noted in the previous subpart, however, public agencies often do not test or provide funding to test products and chemicals which may cause harm. This can be the result of regulatory capture, insufficient funding, or any number of reasons. Reports also indicate that public funding for scientific studies is down in general.[188] Without the assistance of the National Science Foundation, for example, is it possible to count on third parties to adequately study drugs, medical devices, and chemicals to protect safety?

The knowledge remedy provides a backstop when funding for studies either before dissemination of a product or toxin, or after its dissemination, is not available. The drawback of the knowledge remedy, as compared to publicly funded research, is that it is an after-the-fact remedy because it is only available in cases where the plaintiff can show that the defendant has created a dangerous condition, even if the plaintiff does not have enough information to prove causation. Still, late is better than never in many of these cases. For example, how long would DuPont have continued to spill C8 into the local water in the absence of litigation?

3. Legitimacy: Avoids "Junk Science" Accusation.—One of the most powerful arguments against mass tort litigation in general is the allegation that juries rely on so-called junk science when they hold manufacturers accountable. This accusation erodes the legitimacy of the court system which is built on accuracy of decision-making and trial as a search for truth.

The poster child for the accusation of junk science in the courts was the silicone breast implants case involving Dow Corning.[189] That was in part a case of regulatory failure because the Food and Drug Administration (FDA) did not have the power to require testing of the product when it was first made available. That power was only statutorily granted many years after this type

187. *Id.* at 20.

188. David R. Johnson, *With Federal Funding for Science on the Decline, What's the Role of a Profit Motive in Research?*, CONVERSATION (June 5, 2018, 6:46 AM), http://theconversation.com/with-federal-funding-for-science-on-the-decline-whats-the-role-of-a-profit-motive-in-research-93322 [https://perma.cc/MT6C-X26J] (describing the downward trend in federal funding for science). For underlying data, see Am. Ass'n for the Advancement of Sci., *Historical Trends in Federal R&D* (June 2019), https://www.aaas.org/programs/r-d-budget-and-policy/historical-trends-federal-rd [https://perma.cc/968F-EF8U].

189. *See generally* MARCIA ANGELL, SCIENCE ON TRIAL: THE CLASH OF MEDICAL EVIDENCE AND THE LAW IN THE BREAST IMPLANT CASE (1996) (recounting the controversy surrounding the case and the medical evidence presented therein).

of implant went on the market. There was evidence that the company hid information about leakage of silicone from its implants and some evidence that leaking silicone could be harmful.[190] Lawsuits were brought alleging that the leakage caused autoimmune disease.[191] Studies conducted in the 1990s showed that the silicone leaks could not be linked to the disease but not before the company went bankrupt as a result of the litigation.[192] Later studies showed an association between autoimmune disorders and breast implants, however, raising questions about the initial reaction to this litigation.[193]

For a more recent example, consider the legal exposure of Bayer AG after purchasing the agricultural company Monsanto discussed earlier. With litigation around Monsanto's herbicide Roundup expanding, Bayer's market capitalization was slashed by roughly $50 billion.[194] Yet evidence in these cases, especially evidence of causation, is highly contested. In the Roundup litigation, for example, there were dueling experts on both sides. The first trial resulted in a $289 million verdict for the plaintiff.[195] On appeal, a group of doctors filed an amicus brief arguing that the juror's decision in the first Roundup trial was based on "emotional manipulation" rather than "accepted scientific evidence and rigorous scientific reasoning."[196]

This was a case about which the jurors cared deeply enough to write to the judge defending their verdict as he considered a motion to remit the

190. Deborah R. Hensler & Mark A. Peterson, *Understanding Mass Personal Injury Litigation: A Socio-Legal Analysis*, 59 BROOK. L. REV. 961, 992–93 (1993). The FDA did not have the power to regulate medical devices when silicone implants entered the market. *Id.* When Congress passed legislation giving the FDA that authority, silicone implants stayed on the market while the FDA considered their safety. *Id.* Internal documents from Dow Corning eventually emerged stating the potential harmful effects of the implants. *Id.*

191. *Id.* at 996.

192. This is the traditional story. For a description, citing cases denying the admissibility of expert evidence of causation, see Michael D. Green & Joseph Sanders, *Admissibility Versus Sufficiency: Controlling the Quality of Expert Witness Testimony*, 50 WAKE FOREST L. REV. 1057, 1078 (2015).

193. Christopher Coroneos et al., *US FDA Breast Implant Postapproval Studies: Long-term Outcomes in 99,993 Patients*, 269 ANNALS OF SURGERY 30–36 (2019).

194. Ruth Bender, *Bayer's Roundup Problem Slashes Its Market Value*, WALL ST. J. (May 19, 2019, 6:11 PM), https://www.wsj.com/articles/bayers-roundup-woes-send-investors-fleeing-11558266059 [https://perma.cc/4UXF-M84V] (stating that Bayer had lost 45% of its market capitalization due to concerns about liability from Roundup litigation).

195. Holly Yan, *Jurors Give $289 Million to a Man They Say Got Cancer from Monsanto's Roundup Weedkiller*, CNN (Aug. 11, 2018, 9:28 PM), https://www.cnn.com/2018/08/10/health/monsanto-johnson-trial-verdict/index.html [https://perma.cc/9SHF-WUSF].

196. Amanda Bronstad, *California Physicians: Jury Disregarded Science in $289M Roundup Verdict*, LAW.COM (Sept. 6, 2019, 4:13 PM), https://www.law.com/therecorder/2019/09/06/california-physicians-jury-disregarded-science-in-289m-roundup-verdict/ [https://perma.cc/C3KN-6MQZ].

amount.[197] It is extremely rare for jurors to write such letters and demonstrates how important these cases are to the citizens who sit as adjudicators as well as the plaintiffs and defendants. The fact that these cases are important, that jurors listen carefully to the evidence and believe they are impartial, demonstrates how important to the sociological legitimacy of the system it is to avoid inaccurate accusations of junk science when, what in fact is at issue, is preventable scientific uncertainty. In situations such as that involving Roundup, the issue is not that some of the evidence relied on was quackery. Rather, it is that the studies remain inconclusive, and the company believes it should not be held liable based on such inconclusive studies. The result, unfortunately, is a full-frontal attack on the justice system itself rather than a debate about the quantum of evidence.

The knowledge remedy could mitigate such attacks by first ordering the production of adequately funded, independent research and only then trying liability. This would avoid situations such as the Dow Corning breast implant cases but also enable litigation in appropriate situations such as that involving DuPont's pollution with C8.

4. Avoids Bankruptcy on the One Hand and Preapproval on the Other.— Concerns over products and chemicals that are mass-produced could lead to two outcomes. The first is that the government will require preapproval, and the second is that litigation will result in bankruptcy. The knowledge remedy may provide a middle ground between these two choices, limiting exposure to bankruptcy while not requiring testing prior to market. Testing prior to market may be a better solution for avoiding harm to thousands and consequent litigation. For example, some have argued that the problem at the root of the breast implants litigation against Dow Corning was the defendant company's failure to test its products.[198] But for purposes of this paper, I assume that such a proposal would have difficulty being implemented due to industry objections. The knowledge remedy is a second-best option.

One possibility for avoiding mass tort litigation and potential bankruptcy is to require preapproval of products and chemicals before they can be sold, used, or released into the air and water. Too many products are never tested. For example, Dow Corning's breast implants were not tested

197. Tina Bellon, *Jurors Urge Judge to Uphold $80 Million Roundup Verdict Against Bayer*, REUTERS (July 8, 2019, 1:12 PM), https://www.reuters.com/article/us-bayer-glyphosate-lawsuit/juror-urges-us-judge-to-uphold-80-million-roundup-verdict-against-bayer-idUSKCN1U3263 [https://perma.cc/9D55-CN86].

198. *See, e.g.*, Rebecca S. Dresser et al., *Breast Implants Revisited: Beyond* Science on Trial, 1997 WIS. L. REV. 705, 707 ("[T]he silicone gel breast implant controversy arose because manufacturers, physicians, and federal officials allowed the devices to be used without adequate safety data.").

before being used on millions of women because the legal regime at that time did not require FDA approval for such medical devices. Had the implants been tested before being used on the population, they might not have been allowed to be sold because of their propensity to leak, or the regulators might have found that the leakage was not a cause for concern in terms of creating other health problems. In the absence of testing and indicia that signal a flaw on their face, the result is litigation.

Where there are indicia of wrongdoing or a cover-up, the likelihood of large verdicts (and therefore entity-threatening litigation) rises. Yet this threat is not sufficient to induce companies to test, as the stories above indicate. Accordingly, in the absence of reliable studies (which is to say, studies not captured by industry), the knowledge remedy is a solution that may prevent bankruptcy in cases like *Dow Corning* while avoiding preapproval.

B. Arguments Against

This subpart considers four arguments against the knowledge remedy.

1. Delays Plaintiffs' Recovery.—A significant objection to the knowledge remedy is that it delays plaintiffs' recovery, likely for years. This is because studies properly conducted take time. During that time, of course, the plaintiffs do not receive recompense even if they will ultimately be found entitled to it.

Further, in the condition of preventable scientific uncertainty, plaintiffs may benefit because the unpredictability of results may end up in their favor. The silicone breast implants cases are an example of this. In those cases, scientific uncertainty, combined with evidence of misconduct as to the leaking of the implants, resulted in payouts to plaintiffs. Plaintiffs ended up receiving a payment that they would not have received if a knowledge remedy had been awarded. In addition, if uncertainty falls in their favor and indeed their injuries were caused by the defendant, payment will be quicker than under a regime that imposes a knowledge remedy. At the same time, if the injury was caused by the defendant's product but the plaintiffs ultimately do not prevail at trial for lack of proof, then the knowledge remedy would lead to a better outcome for plaintiffs. From a systemic perspective, of course, it is preferable only to require a defendant to pay when there is causation and not when causation cannot be shown.

There is not much to say about this objection other than that delay is a significant cost of the knowledge remedy to injured plaintiffs whose injuries were in fact caused by the defendant and who would have won their suits under conditions of uncertainty. If the knowledge remedy produces greater sociological legitimacy and puts to rest allegations of "junk science" that plague the legal system, this trade-off is likely worth the potential benefits to plaintiffs of unpredictability resulting from preventable scientific

uncertainty. If it merely creates another front for making junk science accusations, however, the trade-off may not be worthwhile.

2. Creates a New Duty to Test.—So far, this Article has argued that the knowledge remedy is a remedy for violation of a duty to the plaintiff. One might argue, however, that the knowledge remedy bootstraps a duty to test. If the knowledge remedy imposes a testing regime and if the remedy is meant to fit the wrong, then the wrong is the failure to conduct that testing. My research reveals no court that has recognized a common law duty to test, only a duty to warn once information is available. Of course, regulators can require testing, and they do, but the number of lawsuits concerning chemicals and drugs that are proven to cause disease and never were tested indicates that there is underregulation.[199]

Wendy Wagner has suggested a change to the common law standard: giving immunity to companies that test their products and find them to be safe and penalizing companies that fail to test their products.[200] The penalty would work as follows.[201] The common law would recognize a duty to test with the threshold for minimal scientific testing to be established by either an independent panel or some judicially created threshold, such as two short-term laboratory studies. In suits involving chemicals or products that did not meet the threshold for minimal testing, the plaintiff would be entitled to a presumption that the product caused her harm if she could show such harm was a biologically plausible result of exposure. If the threshold was met, the traditional rules of tort law would apply. This would create an *ex ante* incentive to test, at least to the legally required threshold, in order to avoid liability and counteract the apparent preference for companies to bury their heads in the sand and hope that liability will be avoided by lack of knowledge and the plaintiff's inability to prove her case.

A knowledge remedy is similar to Wagner's proposal in the sense that the threshold for imposing the remedy would not be reached if the company were to test. In many of the cases discussed here, it is the failure to test despite evidence indicating a danger that triggers the knowledge remedy. If the company had tested the product, it would likely avoid the finding of wrongdoing in the creation of a dangerous condition for the plaintiff. Although this Article has argued that applying the duty to aid a plaintiff once

199. *See* Wendy Wagner, *When All Else Fails: Regulating Risky Products Through Tort Litigation*, 95 GEO. L.J. 693, 695, 714–16 (2007) (describing information limitations of regulators); Dresser et al., *supra* note 198, at 707 ("[T]he silicone gel breast implant controversy arose because manufacturers, physicians, and federal officials allowed the devices to be used without adequate safety data.").

200. Wagner, *supra* note 30, at 833.

201. For details of the proposal I summarize next, see *id.* at 834–36.

the defendant has created a dangerous condition is a principle known in the common law, this is a new context for the application of that principle. Medical monitoring can provide a precedent, but courts have not explicitly adopted this rationale.[202]

In some ways, the knowledge remedy provides an illustration of how remedies and wrongs intermingle,[203] just as it illustrates the overlap between procedure and the substantive law in its similarity to civil discovery. The underlying wrong that the knowledge remedy seeks to address is a violation of a duty to take care with respect to the design of products, the duty to warn if a product is dangerous, or the duty not to pollute a neighbor's land, for example. As we have seen, if the defendant has willfully ignored the potential harm caused by its product or toxin, then it may be impossible for the plaintiff to prove causation on her own, even though the adversarial system presumes that she can meet this requirement.

This remedy is appropriate under a theory analogous to the doctrine of unclean hands in equity. Unclean hands is an equitable defense.[204] It was identified early on as a way to punish misconduct even when it could not be shown to be illegal. As Justice Story explained:

> He who has acted in bad faith, resorted to trickery and deception, or been guilty of fraud, injustice, or unfairness will appeal in vain to a court of conscience, even though in his wrongdoing he may have kept himself strictly 'within the law.' . . . Under this maxim, any willful act in regard to the matter in litigation, which would be condemned and pronounced wrongful by honest and fair-minded men, will be sufficient to make the hands of the applicant unclean.[205]

While the unclean hands defense is a shield for a defendant, the knowledge remedy is a sword for the plaintiff. In this sense, unclean hands and the knowledge remedy are mirror images of one another. But they are linked by the general principles that fault shifts the cost of injury and of

---

202. Goldberg & Zipursky, *supra* note 124, at 1710, 1712.

203. *See* Daryl J. Levinson, *Rights Essentialism and Remedial Equilibration*, 99 COLUM. L. REV. 857, 931 (1999) (describing that in private law, such as torts, "the purposes of liability and remedy are the same, and the discourse used to describe both is singular"). Levinson further explained, "[w]e might say that in nonconstitutional law, rights and remedies are *commensurable*." *Id.*

204. *See, e.g.*, EMILY SHERWIN & SAMUEL BRAY, AMES, CHAFFEE, AND RE ON REMEDIES: CASES AND MATERIALS 967 (2d ed. 2018) ("Certain defenses are 'equitable' in the sense that they preclude the plaintiff from requesting equitable relief but do not provide a complete defense against liability.").

205. STORY, *supra* note 90, at § 99; *see also* Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 814 (1945) ("The guiding doctrine in this case . . . is a self-imposed ordinance that closes the doors of a court of equity to one tainted with inequitableness or bad faith relative to the matter in which he seeks relief, however improper may have been the behavior of the defendant."); RESTATEMENT (SECOND) OF TORTS § 940 (AM. LAW INST. 1979) (restating the doctrine of unclean hands).

flexibility in equitable remedies. Both doctrines recognize that the adjustment of the remedies is warranted depending on the circumstances of both parties' conduct. In such instances, a court may consider both illegal conduct and conduct that raises the opprobrium of the court and of ordinary morality. This idea can thus include both a remedy of denying an injunction where one would otherwise be warranted (based on the other side's misconduct) and a remedy of requiring the production of information when it was due to one party's misconduct that the information is unavailable.[206] This explains the award of a knowledge remedy in the accounting context. Lack of information and inability to obtain it, combined with an incentive on the part of the defendant not to create information, justify an equitable approach in the negligence or products liability context because the defendant's conduct placed the plaintiff in danger.

3. Discourages Research.—Awarding a knowledge remedy may have the perverse result of discouraging *ex ante* research and testing that may lead manufacturers to take safety precautions. This is because if defendants know that they will be ordered to test if their products are suspected to be injurious, they may calculate that it is better to wait until they are forced to test by a court and pay for testing at that point. Indeed, as in the current regime, the less companies know about the injuries caused by their products, the greater protection they have against liability. The knowledge remedy will also further delay any payments for injury that they might ultimately make, which inures to their benefit. If the goal is to encourage companies to test, a duty to test would be a more efficient way of encouraging companies to test their products and take needed precautions *ex ante*.

In a first-best world, the Wagner proposal discussed in section IV(B)(2) would be a better approach to the problem of dangerous products and preventable scientific uncertainty. In light of the fact that no duty to test has been recognized despite many instances of wrongful decisions to ignore signs of danger and to manufacture uncertainty as to the risks created by products, the second-best approach of the knowledge remedy is better than nothing.

4. Oversteps the Judicial Role.—A final objection to the knowledge remedy is that it departs from the traditional judicial role. Some may argue that the court usurps the legislative role when it orders an ongoing and complex remedy such as a knowledge remedy. Or some may argue that courts overstep their bounds by awarding a remedy that resembles something that an agency such as the FDA would order before allowing a drug to come to

206. For a general discussion of uncertainty in tort, see ARIEL PORAT & ALEX STEIN, TORT LIABILITY UNDER UNCERTAINTY (2001).

market. For example, the Supreme Court of Michigan, considering whether a negligence claim seeking medical monitoring may lie in the absence of physical injury has stated:

> In the absence of such a requirement, it will be inevitable that judges, as in the instant case, will be required to answer questions that are more appropriate for a legislative than a judicial body: How far from the Tittabawassee River must a plaintiff live in order to have a cognizable claim? What evidence of exposure to dioxin will be required to support such a claim? What level of medical research is sufficient to support a claim that exposure to dioxin, in contrast to exposure to another chemical, will give rise to a cause of action?[207]

This line-drawing problem is ubiquitous in many areas of law and equity where there is an overlap between the judicial and legislative powers. To some extent, every imposition of liability ultimately regulates an industry by creating an incentive to change behavior. And in many cases, the court must determine where immunity ends and obligation begins. For example, consider asking the same questions as those asked by the Michigan court above about the standards of ordinary care or foreseeability in negligence law, or of when a fiduciary duty is owed in agency law.[208] Each of these decisions requires a policy judgment that could be made by a legislature. We can rethink familiar negligence cases along these lines. Does the ordinary duty of care require a barge owner to have an attendant on the barge in case of emergency?[209] It is generally agreed that the owner whose barge has been damaged may bring a suit and that the adjudicator will determine whether the failure to put an attendant on the barge breached the duty of ordinary care.[210] This does not mean, however, that one could not imagine the legislature imposing a duty on barge owners or immunizing them by statute.

Arguably, an order to produce knowledge is less complex and interferes less with legislative prerogatives than structural injunctions, which, although controversial, have been generally accepted in cases of violations of constitutional rights.[211] Indeed, the knowledge remedy falls somewhere

---

207. Henry v. Dow Chem. Co., 701 N.W.2d 684, 691 (Mich. 2005).

208. *See also* Paz v. Brush Engineered Materials, Inc., 949 So. 2d 1, 8 (Miss. 2007) ("This is the type of case in which the Court has held that the common law is malleable, particularly so in the area of torts, and thus this Court can create and discontinue torts in common law.").

209. These are the facts of *United States v. Carroll Towing Co*., 159 F.2d 169, 170–71 (2d Cir. 1947).

210. *See id.* at 173 (describing an owner's duty when mooring a boat as "a function of three variables: (1) The probability that she will break away; (2) the gravity of the resulting injury, if she does; (3) the burden of adequate precautions").

211. *Compare* Owen M. Fiss, *Foreword: The Forms of Justice*, 93 HARV. L. REV. 1, 2 (1979) (arguing in favor of structural injunctions) *with* Douglas Laycock, *Injunctions and the Irreparable Injury Rule*, 57 TEXAS L. REV. 1065, 1074 (1979) (arguing in favor of a somewhat narrower approach).

between compensation remedies recognized in most cases at law and complex structural injunctions on the continuum of judicial intervention. The way to address the line-drawing problem is to look separately at each substantive area of law where a knowledge remedy is proposed rather than to make a general statement about knowledge remedies as exceeding or remaining within the courts' proper sphere of power.

In some cases, the knowledge remedy may be less intrusive than ordinary tort remedies of compensation. Consider again the case of Dow Corning's silicone breast implants. Recall there was evidence that the defendant hid information about leakage of silicone from its implants. Some studies showed that the silicone leaks could not be linked to the disease but not before the company went bankrupt. For some, this is evidence of the tort system gone wrong and of junk science.[212] But others have argued that the problem at the root of the litigation was the defendant company's failure to test its products prior to putting them on the market.[213] What would have happened if the court had imposed a knowledge remedy based on the defendant's initial wrongdoing—the failure to warn of the risk of leaking silicone—and waited on or delayed products liability damages cases until the studies were in? Plaintiffs too would have had to wait until there was sufficient scientific evidence, and sometimes more than one study is necessary. But it might have been a remedy more consistent with the judicial role in equity because it was appropriate to the available information, the development of scientific knowledge, and the wrong alleged.

A final consideration is the competence of courts as an institution to award knowledge remedies. Because judges are generalists, they may not know what technology may be available, not appreciate the costs of conducting studies, and not appreciate the extent to which a single study is unlikely to produce a definitive answer. On the other hand, often mass torts occur because of regulatory failure by other institutions, such as a failure of the FDA to require adequate testing of products[214] or a failure of legislatures to be sufficiently aware of a problem to regulate it. There is a solution in the law to institutional-competence questions such as this, and that is preemption by regulatory agencies. Whether preemption is the optimal solution in light of regulatory failure is a question beyond the scope of this paper. As Catherine Sharkey has argued, regulation and litigation can complement one another,[215] so there remains much to explore.

---

212. *See generally* ANGELL, *supra* note 189 (considering the impact of tort law on American life and the role of science in the courtroom through the prism of the breast implant controversy).

213. Dresser et al., *supra* note 198, at 707.

214. *See* Wagner, *supra* note 199, at 714–16 (describing information limitations of regulators).

215. Catherine M. Sharkey, *The Administrative State and the Common Law: Regulatory Substitutes or Complements?*, 65 EMORY L. REV. 1705, 1706 (2016).

Examples of knowledge remedies in action illustrate that courts are capable of ordering and overseeing these remedies. Even in the most involved example, the C8 Science Panel, a thoughtful and serious scientific process was instituted with the court's approval. Furthermore, the combination of the decline of administrative oversight of chemicals and drugs, the inadequate and declining state and federal budgets for scientific study, and the increase in regulatory capture all militate against the view that the administrative state can be counted on to regulate *ex ante*.

Conclusion

In a society that is increasingly both complex and unwilling to fund research out of the public fisc,[216] a knowledge remedy is a supplement to inadequate administrative regulation, particularly in cases involving toxins or drug-and-device litigation, where tort suits are not preempted. Indeed, the role of civil discovery has been for some time understood as a complement to the administrative state.[217] The knowledge remedy likewise serves as a complement to regulation.

This beneficial externality of the knowledge remedy is also its Achilles' heel in the sense that it challenges the traditional view that remedies, especially remedies in the types of claims generally understood to constitute private law, are to be administered as between the parties themselves, not for the benefit of third parties.[218] Yet the tort system does impact third parties, even when it apparently applies only to the parties before the court, because actors observing the system change their behavior in response to it. They may decide that it is better not to test toxins, for example, because then they will be more likely to win failure to warn claims.[219] Or they may decide that it is better not to invest in researching better pollution-mitigating measures because if such measures exist, a court might include them in an injunction.

---

216. *See supra* note 188 and accompanying text.

217. *See* Stephen N. Subrin, *Fudge Points and Thin Ice in Discovery Reform and the Case for Selective Substance-Specific Procedure*, 46 FLA. L. REV. 27, 35 (1994) ("Clark marveled at how the new procedure would permit litigators to enter the New Deal and to amass the information relevant to policymakers."); *see also* Paul D. Carrington, *Renovating Discovery*, 49 ALA. L. REV. 51, 54 (1997) ("Every day, hundreds of American lawyers caution their clients that an unlawful course of conduct will be accompanied by serious risk of exposure at the hands of some hundreds of thousands of lawyers, each armed with a subpoena power by which misdeeds can be uncovered."); Alexandra D. Lahav, *The Roles of Litigation in American Democracy*, 65 EMORY L.J. 1657, 1690 (2016) (discussing "answerability and accountability" in the enforcement of law).

218. *Cf.* Philip Morris USA v. Williams, 549 U.S. 346, 349 (2007) (holding that a jury may not award punitive damages based on a defendant's conduct towards third parties).

219. Wagner, *supra* note 30, at 774–76 (discussing the incentive for companies not to research their own products, lest they discover defects that plaintiffs or third parties are unlikely to discover on their own).

This is why the line between judicial and legislative action is so difficult to draw; through every decision in the case before it, the court influences the decisions of many others who are not (yet) before the court.

The knowledge remedy has significant trade-offs. When a knowledge remedy is imposed, it may reveal that there is no causal link between a toxin and the alleged harm or between the product and the alleged harm. This means the company will not be required to pay many millions more in damages suits, even if it does mean the company has to invest in research. Where causation is ultimately found, it also means significant delay for plaintiffs as studies are conducted and consensus is reached. Nevertheless, it may be the best choice in a world of second-best choices and limited regulation.